

# EXHIBIT H

CAUSE NO. 2013-DCL-3511-D

SANDRA GARCIA,	)	IN THE DISTRICT COURT
	)	
Plaintiff,	)	
vs.	)	103rd JUDICIAL DISTRICT
	)	
RODOLFO J. WALSS, M.D.,	)	
RODOLFO J. WALSS, M.D.,	)	
P.A., JOHNSON & JOHNSON,	)	
INC. and ETHICON, INC.,	)	
	)	
Defendants.	)	CAMERON COUNTY, TEXAS
_____	)	

DEPOSITION OF  
SUZANNE PARISIAN, M.D.

Phoenix, Arizona  
February 12, 2015  
9:04 a.m.

LEO T. MANKIEWICZ, CR, RMR, CRR  
Arizona Certified Reporter  
Certificate No. 50778

Page 2	Page 4
<p>1</p> <p>2</p> <p>3</p> <p>4</p> <p>5</p> <p>6</p> <p>7</p> <p>8 BE IT REMEMBERED THAT THE DEPOSITION OF</p> <p>9 SUZANNE PARISIAN, M.D.</p> <p>10 was taken on behalf of Defendants, at the Hilton Phoenix</p> <p>11 Suites, 10 East Thomas Road, Phoenix, Arizona,</p> <p>12 commencing at 9:04 a.m., on Thursday, February 12, 2015,</p> <p>13 before Leo T. Mankiewicz, Arizona Certified Reporter,</p> <p>14 Certificate No. 50778, pursuant to Notice of Deposition.</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p>1 INDEX</p> <p>2</p> <p>3 PAGE</p> <p>4 Proceedings 8</p> <p>5 Recess - 10:55 a.m. to 11:04 a.m. 92</p> <p>6 Luncheon Recess - 12:24 p.m. to 1:10 p.m. 166</p> <p>7 Recess - 2:39 p.m. to 2:59 p.m. 252</p> <p>8 Recess - 3:29 p.m. to 3:43 p.m. 277</p> <p>9 INDEX OF EXAMINATION</p> <p>10 Page</p> <p>11 WITNESS: SUZANNE PARISIAN, M.D.</p> <p>12 Witness Sworn .....8</p> <p>13 Examination by Mr. Hutchinson .....8</p> <p>14 Examination by Mr. Lundquist .....281</p> <p>15 Further Examination by Mr. Hutchinson .....302</p> <p>16 EXHIBITS</p> <p>17 Ex. No. Description Page</p> <p>18 1 A four-page photocopy of Defendants Johnson &amp; ....13</p> <p>19 Johnson and Ethicon, Inc.'s Notice of</p> <p>20 Intention to Take the Oral Deposition of Dr.</p> <p>21 Suzanne Parisian and Subpoena Duces Tecum.</p> <p>22</p> <p>23 2 A collective exhibit consisting of the file .....16</p> <p>24 of Dr. Suzanne Parisian in the present matter,</p> <p>comprised of two three-inch binders, one</p> <p>entitled, "TVMS Docket, TVT Secur," and the</p> <p>other bearing a case caption and "Documents -</p> <p>TVT Secur," containing various tabbed sections</p> <p>of documents, as well as an approximately</p> <p>one-inch thick stack of various documents.</p> <p>(cont.)</p>
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<p>1 APPEARANCES:</p> <p>2</p> <p>3 For the Plaintiff:</p> <p>4 Clark, Love &amp; Hutson, G.P.</p> <p>5 440 Louisiana Street, Suite 1600</p> <p>6 Houston, Texas 77002</p> <p>7 BY: WILLIAM W. LUNDQUIST, ESQ.</p> <p>8 Shepherd, Scott, Clawwater &amp; Houston, LLP</p> <p>9 2777 Allen Parkway, 7th floor</p> <p>10 Houston, Texas 77019-2133</p> <p>11 BY: CYNTHIA L. FREEMAN, ESQ.</p> <p>12 (by telephone conference)</p> <p>13 For the Defendants:</p> <p>14 Butler Snow LLP</p> <p>15 Renaissance at Colony Park, Suite 1400</p> <p>16 Ridgeland, Mississippi 39158-6010</p> <p>17 BY: CHAD R. HUTCHINSON, ESQ.</p> <p>18</p> <p>19 Roerig, Oliveira &amp; Fisher, LLP</p> <p>20 10225 North 10th Street</p> <p>21 McAllen, Texas 78504</p> <p>22 BY: DAVID OLIVEIRA, ESQ.</p> <p>23</p> <p>24</p>	<p>1 EXHIBITS (cont.)</p> <p>2 Ex. No. Description Page</p> <p>3 3 A 16-page photocopy of the Curriculum Vitae .....17</p> <p>4 of Suzanne Parisian, M.D.</p> <p>5</p> <p>6 4 A 20-page photocopy of Plaintiff's .....25</p> <p>7 Designation of Expert Witnesses.</p> <p>8 5 A 10-page photocopy of a document bearing the .....29</p> <p>9 present case caption and the heading, "Suzanne</p> <p>10 Parisian, M.D., List of Documents Provided or</p> <p>11 Identified for Review in the above Referenced</p> <p>12 Lawsuit," referred to as the "reliance list"</p> <p>13 in this deposition.</p> <p>14</p> <p>15 6 A 24-page photocopy of an IFU, or .....125</p> <p>16 Instructions For Use document for the Gynecare</p> <p>17 TVT Secur System, bearing Bates numbers</p> <p>18 ETH.MESH.02340568 through -0591.</p> <p>19 7 A 16-page photocopy of a Patient Brochure for ...125</p> <p>20 Gynecare TVT, bearing Bates numbers</p> <p>21 ETH.MESH.08003295 through -3302. (As presented</p> <p>22 at the deposition, this exhibit has blank</p> <p>23 pages inserted every other page.)</p> <p>24 8 An eight-page photocopy of a publication of .....181</p> <p>the U.S. Food and Drug Administration</p> <p>entitled, "General Controls for Medical</p> <p>Devices."</p> <p>9 A 41-page photocopy of a document issued by .....184</p> <p>the Food and Drug Administration, Center for</p> <p>Devices and Radiological Health, and Center</p> <p>for Biologics Evaluation and Research,</p> <p>entitled, "The 510(k) Program: Evaluating</p> <p>Substantial Equivalence in Premarket</p> <p>Notifications [510(k)], Guidance for Industry</p> <p>and Food and Drug Administration Staff,"</p> <p>issued July 28, 2014.</p> <p>(cont.)</p>

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1 EXHIBITS (cont.)  
2 Ex. No. Description Page  
3 10 A seven-page photocopy of a letter on the .....190  
4 letterhead of Department of Health, Education  
5 and Welfare, Public Health Service, Consumer  
6 Protection and Environmental Health Service,  
7 Food and Drug Administration, from B.H.  
8 Minchew, M.D. to Ethicon, Inc. reflecting  
9 approval of NDA 16-374 for a Prolene  
10 Polypropylene Suture material, dated April 16,  
11 1969, bearing Bates numbers ETH.MESH.09625731  
12 through -737.  
13 11 A 47-sheet, double-sided photocopy of a .....199  
14 LexisNexis printout of a document entitled, "I  
15 of 28 documents, Federal Register, 21 CFR Part  
16 878, General and Plastic Surgery Devices,  
17 General Provisions and Classification of 54  
18 Devices, Docket No. 78N-2646, 47 FR 2810,"  
19 dated January 19, 1982.  
20 12 A 13-page photocopy of a letter on the .....202  
21 letterhead of Department of Health and Human  
22 Services, Food and Drug Administration, from  
23 Robert L. Sheridan, Director of Device  
24 Evaluation to Mr. Walter S. Hennig of United  
States Surgical Corporation, Re:  
Reclassification of Nonabsorbable Polypropylene  
Surgical Suture, Docket Number 88P-0173, dated  
July 5, 1990, bearing Bates numbers  
ETH.MESH.09634664 through -4676.  
13 A four-page photocopy of a letter on the .....215  
letterhead of Department of Health & Human  
Services, Food and Drug Administration, from  
Benjamin R. Fisher, Ph.D. to Gregory R. Jones  
of Ethicon, Inc., Re: K974098, declaring  
substantial equivalence for the TVT system,  
dated September 28, 2012, bearing Bates  
numbers ETH.MESH.10040062 through -0065.  
14 A 122-sheet, double-sided photocopy of a .....220  
series of documents, labeled as a group,  
"Traditional 510(k) Notification, Gynecare TVT  
Secur System, bearing Bates numbers

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1 EXHIBITS (cont.)  
2 Ex. No. Description Page  
3 15 A 20-page photocopy of a letter on the .....227  
4 letterhead of Department of Health & Human  
5 Services, Food and Drug Administration, from  
6 Carl A. Larson, Ph.D., of the Office of Device  
7 Evaluation, Re: N16374/S34, Prolene  
8 Polypropylene Suture, expressing approval of a  
9 PMA supplement, dated October 7, 1988, with  
10 attachments, bearing Bates numbers  
11 ETH.MESH.09634299 through -4318.  
12 16 A four-page photocopy of a document on the .....270  
13 letterhead of AUGS and SUFU, entitled,  
14 "Position Statement on Mesh Midurethral Slings  
15 for Stress Urinary Incontinence," dated  
16 January 3, 2014.  
17 ---o0o---  
18  
19  
20  
21  
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23  
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Page 8

1 Thursday, February 12, 2015  
2 9:04 a.m.  
3 PROCEEDINGS  
4 ---o0o---  
5 SUZANNE PARISIAN, M.D.,  
6 CALLED AS A WITNESS, HAVING BEEN DULY  
7 SWORN, TESTIFIED AS FOLLOWS:  
8 ---o0o---  
9 EXAMINATION BY MR. HUTCHINSON  
10 BY MR. HUTCHINSON:  
11 Q Good morning, Dr. Parisian. How are you  
12 doing?  
13 A Fine.  
14 Q My name is Chad Hutchinson. I represent  
15 Johnson & Johnson and Ethicon in this case. I'm here to  
16 take your deposition, do you understand that?  
17 A Yes, sir.  
18 Q You've been deposed before, correct?  
19 A Yes, sir.  
20 Q You understand you're subject to the penalty  
21 of perjury?  
22 A Yes, sir.  
23 Q If you don't understand one of my questions,  
24 will you let me know?

Page 9

1 A Yes, sir.  
2 Q Otherwise, I'm going to assume you understood  
3 my question. Is that fair?  
4 A Yes, sir.  
5 Q You've been offered as the plaintiff's expert  
6 in the Garcia case, is that right?  
7 A Yes, sir.  
8 Q In what field?  
9 A For FDA regulatory issues.  
10 Q Is that your specialty?  
11 A Yes, sir.  
12 Q Any other specialties?  
13 A Well, I have other specialties, but that's  
14 where I see my role, as an FDA regulatory expert.  
15 Q In this case?  
16 A Yes, sir.  
17 Q Okay, any other roles in this case?  
18 A No, sir.  
19 Q Have you ever been retained as an expert  
20 witness in a mesh case before this one?  
21 A Yes.  
22 Q And which one?  
23 A I believe I was involved with the C.R. Bard  
24 Marlex mesh. I was involved with other surgi- -- AMS

<p style="text-align: right;">Page 10</p> <p>1 mesh, I've been involved with Boston Scientific's 2 transvaginal mesh. Those are the ones I recall. Oh, 3 no, Kugel, Kugel mesh. 4 Q And you testified against the manufacturer in 5 all those cases? 6 A Yes, sir. 7 Q Are you still working in an expert capacity 8 for any of those manufacturers? 9 A You mean for those cases? Yes, sir. 10 Q Approximately how many cases? 11 A Right now, this is the only mesh case I have. 12 Q Against Ethicon? 13 A No, against anybody. I don't have any 14 active -- I'm still involved, but I don't have any 15 active cases that I'm aware of. 16 Q Okay. Well, in how many cases have you been 17 providing expert testimony against manufacturers of mesh 18 products? 19 A Well, those would be the issues. 20 Q How many cases are we talking about? 21 A I don't know, because they're MDLs. I was the 22 expert for the AMS MDL. I don't know how many cases 23 were in that before it settled, and then it was like, 24 I think I gave a deposition for one case that wasn't in</p>	<p style="text-align: right;">Page 12</p> <p>1 was Clinical Innovations, so I was their expert. 2 Q And how long ago was that? 3 A That was several years ago. 4 Q Over 20? 5 A No, no, no, not over 20. It was actually, 6 I think it was actually, like, six years ago. It went 7 off my five-year list, but -- and then when I first 8 started out, if you want my full -- I was also the 9 expert for pedicle screws for industry. So I've 10 testified for industry, I've testified for hospitals, 11 I've testified for industry versus industry. So not 12 every case is a case like this case. 13 Q You've never testified for a defendant in 14 court, have you? 15 A Yes, I have, in court, yes, sir, but I believe 16 it was a hospital, Wash- -- hospital, Seattle Children's 17 Hospital. There wouldn't be any reason I wouldn't, if 18 I accepted a case. 19 Q Have you ever turned down a pharmaceutical 20 medical device case for a plaintiff? 21 A Oh, yes. I don't take every case given to me. 22 Q I'm handing you what I've marked as Exhibit 1 23 to your deposition. Do you have that in front of you? 24 A Yes, sir.</p>
<p style="text-align: right;">Page 11</p> <p>1 the MDL, or -- no, two, two. So I don't know how big 2 the MDLs are. I've just been hired for litigation. 3 Q Okay, but you would be an expert for each and 4 every plaintiff in that -- in the MDLs, correct? 5 A Yes, sir, if they needed me for the case, yes, 6 sir. So I don't know how big those MDLs are; unlike 7 this case, which is here, I know it's a single 8 plaintiff. 9 Q For -- let's talk about Ethicon in particular, 10 okay? 11 A Yes, sir. 12 Q How many mesh cases have you been involved in 13 against Ethicon? 14 A Only this one. 15 Q And if my math is correct, since 1997, you've 16 testified in court 81 times for a plaintiff, is that 17 right? 18 A Yes, sir. Those are the -- those aren't all 19 the cases I've had, but those are the ones that have 20 gone to court. 21 Q And you've always testified for the plaintiff 22 in pharmaceutical and medical device cases? 23 A In court, yes, but I have been an expert 24 witness for a medical device manufacturer. I think it</p>	<p style="text-align: right;">Page 13</p> <p>1 (Whereupon, Exhibit 1 was marked for 2 identification.) 3 BY MR. HUTCHINSON: 4 Q And if you'll look on the last page, we had 5 asked for some documents. Do you see those? 6 A Yes, sir. 7 Q Did you bring those documents with you today? 8 A I didn't bring my curriculum vitae, but 9 I thought you had received that. I've tried to bring 10 everything else that I have, and then I think I helped 11 generate a list of documents I've relied on. 12 Q Okay, and just so the record is clear, you've 13 brought everything that you have that is responsive to 14 the document request 1 through 9, correct? 15 A Yes, sir. I have brought what we call my 16 file. 17 Q And you have your file in front of you, is 18 that correct? 19 A Yes, sir. 20 Q Why don't we do this. And just for the 21 record, your file consists of two black binders, one of 22 which is called "TVT Secur" on the front, and the other 23 one is called, "Documents-TVT Secur," right? 24 A Yes, sir.</p>

<p style="text-align: right;">Page 14</p> <p>1 Q And each document has a bunch of tabs, and a 2 lot of documents that you've reviewed for this case? 3 A Yes, sir, and it's all my handwriting and my 4 tabs. 5 Q And then we have a separate stack of loose 6 paper in front of you that you've brought responsive, 7 correct? 8 A Yes, sir. 9 Q And what does this stack represent? 10 A Okay. It would be the rest of my file, and it 11 represents my designation as an expert witness, what 12 we're going to talk about today, the amended report of 13 John Miklos, a list of documents that I've relied on, 14 the deposition notice, my billing records, all the 15 records that I've generated as well as the ones getting 16 ready for the deposition today that hasn't been billed; 17 some agreement for the protective order; the Has French 18 National Authority for Health report, November 2006; 19 some other articles that I've found, we'll put it that 20 way. Those are articles I've found. 21 So the medical literature that I have here, 22 the searches are from my -- I've obtained those, and the 23 advertising from Johnson &amp; Johnson for the Ethisorb 24 product; my communication that came with my binder; the</p>	<p style="text-align: right;">Page 16</p> <p>1 handwriting and highlights in them, correct? 2 A Yes, sir. 3 Q And all the handwriting and highlights were 4 done by you, correct? 5 A Yes, sir. 6 Q And nobody else. 7 A Yes, sir. 8 Q And why don't we go on and mark -- 9 A Except for the ones that are printed with a 10 highlighting. If they're yellow, they're mine. 11 Q And let's go ahead and mark as Exhibit -- as a 12 collective Exhibit 2 your two black notebooks and the 13 loose paper, as Exhibit 2, okay? 14 A Um-hum. 15 MR. LUNDQUIST: Well, obviously, when we -- 16 I mean, we can receive copies. 17 MR. HUTCHINSON: We'll have copies of them. 18 MR. LUNDQUIST: Okay, all right. 19 (Whereupon, Exhibit 2 was marked for 20 identification.) 21 BY MR. HUTCHINSON: 22 Q And does Exhibit 2 reflect every sheet of 23 paper that you used to formulate your opinion in this 24 case?</p>
<p style="text-align: right;">Page 15</p> <p>1 510(k) for AMS products, which was one of the -- another 2 product, as well as the 510(k) -- I'll give -- K021263, 3 which was for the SPARC Sling System; the Codman 4 Ethisorb Dura Patch 510(k), K991413; the 510(k) 5 clearance for the Gynecare TVT Secur device, and that's 6 K052401. 7 I had done a search at one time of the suture 8 materials that are used for the mesh, the PDS absorbable 9 product, and I believe Vicryl. So I brought those 10 510(k)'s that are stapled together. 11 And then, let's see, I brought the patents -- 12 trademark for the Monitorr, M-O-N-I-T-O-R-R device; and 13 then last night, I brought -- I went and did a really 14 quick look at the Medical Device Reports for Gynecare 15 TVT, and I've brought those documents, kind of 16 summarized together. 17 Q Okay, and that was for Gynecare TVT and not 18 TVT Secur, right? 19 A No, it was the -- only way to get Secur is if 20 you use TVT Gynecare and then Secur. So I did do it 21 looking at Secur, but it had to come up under TVT 22 Gynecare. 23 Q Okay, and in this one stack of loose 24 documents, and the two black notebooks, they have some</p>	<p style="text-align: right;">Page 17</p> <p>1 A No, no, because I mean, I've had a history of 2 mesh products before. So you couldn't bring every 3 document that -- because I've dealt with mesh and the 4 same with the other vaginal mesh products, and I mean, 5 my knowledge of these types of products go back to 6 ProtoGen, which is a long time ago. So it's not -- but 7 the ones that I have specifically used for Ethicon are 8 here. 9 Q Okay. Well, that was my question, thank you. 10 So Exhibit 2 would represent all of the materials that 11 you relied on in this particular case to reach opinions, 12 correct? 13 A With the caveat that there's a background that 14 I have. I can't bring that. That's been acquired over 15 years. 16 Q I understand. All right, thank you. Let's 17 look at your CV. We'll mark it as Exhibit 3. 18 I recognize it's in here, but I've got a clean copy. 19 A Thank you. 20 (Whereupon, Exhibit 3 was marked for 21 identification.) 22 BY MR. HUTCHINSON: 23 Q This is the most current copy of your CV? 24 A Yes. I believe -- I think so. I'm not sure.</p>

<p style="text-align: right;">Page 18</p> <p>1 There's nothing really significantly different. I just</p> <p>2 might have had a different date on it, but I haven't</p> <p>3 done anything different.</p> <p>4 Q All publications are included on your CV?</p> <p>5 A Yes, sir.</p> <p>6 Q You've never published anything in a</p> <p>7 peer-reviewed journal, have you?</p> <p>8 A Well, no. I have in terms of when I was in</p> <p>9 developmental biology.</p> <p>10 Q Have you ever published anything on a cervical</p> <p>11 mesh?</p> <p>12 A No.</p> <p>13 Q Proline?</p> <p>14 A No.</p> <p>15 Q TVT Secur?</p> <p>16 A No.</p> <p>17 Q Anything on SUI?</p> <p>18 A No, sir.</p> <p>19 Q You understand SUI means stress urinary</p> <p>20 incontinence?</p> <p>21 A Yes, and I began looking at SUI issues when</p> <p>22 I was at the FDA.</p> <p>23 Q You've never published on dyspareunia or</p> <p>24 pelvic pain?</p>	<p style="text-align: right;">Page 20</p> <p>1 A I've actually consulted for firms for devices</p> <p>2 for stress urinary incontinence that are radiofrequency</p> <p>3 devices for treating that.</p> <p>4 Q We'll get to that in a minute, but let's stay</p> <p>5 on hands-on testing.</p> <p>6 A I haven't done any hands-on testing, I just</p> <p>7 consulted.</p> <p>8 Q For any type of SUI device?</p> <p>9 A Yes, sir. No, I did. I did do that.</p> <p>10 Q Oh, you did do that.</p> <p>11 A Yeah, I did do consulting for an SUI device,</p> <p>12 but I didn't do hands-on testing. I did regulatory</p> <p>13 consulting.</p> <p>14 Q All right. Just so the record's clear, you've</p> <p>15 never done any hands-on testing for any type of stress</p> <p>16 urinary device, correct?</p> <p>17 A Correct.</p> <p>18 Q Let's talk about your correspondence with</p> <p>19 Ms. Garcia's counsel. When were you first contacted in</p> <p>20 this case?</p> <p>21 A I don't -- I think around sometime in the</p> <p>22 summer, in July-ish. I was looking at buying a house,</p> <p>23 and he caught me, and I was in the middle of talking to</p> <p>24 realtors and stuff.</p>
<p style="text-align: right;">Page 19</p> <p>1 A No.</p> <p>2 Q Let's talk about presentations. Are all the</p> <p>3 presentations that you've given included within your CV?</p> <p>4 A Yes, sir.</p> <p>5 Q Have you ever presented on surgical mesh?</p> <p>6 A No, sir.</p> <p>7 Q Proline?</p> <p>8 A No, sir.</p> <p>9 Q TVT Secur?</p> <p>10 A No, sir.</p> <p>11 Q SUI?</p> <p>12 A No, sir.</p> <p>13 Q Dyspareunia or pelvic pain?</p> <p>14 A No, sir.</p> <p>15 Q Your research experience, is all that included</p> <p>16 within your CV marked as Exhibit 3?</p> <p>17 A Yes, sir. I haven't done any hands-on</p> <p>18 testing. I think that's what you're asking, about mesh.</p> <p>19 No.</p> <p>20 Q No hands-on testing for any type of surgical</p> <p>21 mesh?</p> <p>22 A That is correct.</p> <p>23 Q And no hands-on testing for any type of</p> <p>24 product to treat stress urinary incontinence?</p>	<p style="text-align: right;">Page 21</p> <p>1 Q He called you on your cell phone?</p> <p>2 A Yeah, and I didn't buy the house, so</p> <p>3 I remembered that --</p> <p>4 Q That was in the summer of 2014?</p> <p>5 A Yes, sir.</p> <p>6 Q And what were you asked to do in this case?</p> <p>7 A I was asked if I would accept looking at the</p> <p>8 case. I mean, I was familiar with vaginal mesh from AMS</p> <p>9 and I had had to look at issues with Ethicon before, so</p> <p>10 he asked if I would look at an Ethicon issue.</p> <p>11 Q Okay, and what did you tell him you'd do?</p> <p>12 A I told him -- what did I tell him I'd do?</p> <p>13 I told him I would look at it and I'd give him opinions</p> <p>14 as to whether I would want to take the case.</p> <p>15 Q Have you ever spoken -- and who was that that</p> <p>16 called you, Mr. Lundquist?</p> <p>17 A Mr. Lundquist. He has my number.</p> <p>18 Q Had you ever spoken with Mr. Lundquist before</p> <p>19 that first time?</p> <p>20 A Yes, I had worked with them on, I believe --</p> <p>21 AMS? Yes, AMS, for the MDL.</p> <p>22 Q Had you worked with Mr. Lundquist and his firm</p> <p>23 for any other MDLs?</p> <p>24 A Paxil, I was involved with Paxil, and I'm not</p>



Page 22

1 sure who all the people are in MDLs. I know was with  
2 Trasyolol, I was involved.

3 Q Trasyolol?

4 A Trasyolol; and Paxil, and I'm not sure what  
5 other ones I've been involved with.

6 Q Okay.

7 A Those are the ones I directly spoke to members  
8 of his firm.

9 Q That's at least four MDLs that you've been  
10 working with Mr. Lundquist's firm on, correct?

11 MR. LUNDQUIST: Objection, form.

12 THE WITNESS: Well, I'm not working on an MDL,  
13 I'm just working on this particular case. So that would  
14 be that they were part of an MDL group, as you know,  
15 which could be hundreds of attorneys, for Paxil and --  
16 so it was really -- was it four? Yeah, but this isn't  
17 an MDL, as far as I know.

18 BY MR. HUTCHINSON:

19 Q Right. When did you first start working with  
20 Mr. Lundquist's firm?

21 A Mr. Lundquist -- the firm? The firm, the  
22 first time I met -- that I remember meeting somebody  
23 from that firm was for Paxil, which would have been  
24 years ago.

Page 23

1 Q How many years ago?

2 A I'm not sure when that was. I'm not sure --  
3 I met them at the Kilker trial was the first time I met  
4 someone from his firm, and I don't know when that was.  
5 That was the only Paxil trial in Philadelphia.

6 Q Would that have been more than 10 years ago?

7 A I don't think it was that long ago. It was  
8 less than that. It was probably, I don't know, eight  
9 years ago, four years ago?

10 Q Have you met with Mr. Lundquist before today's  
11 deposition?

12 A Yes, sir.

13 Q How many times have you met?

14 A For this deposition, I met with him once.  
15 I met with him for three and a half hours, and that's  
16 where we put together what my opinions would be for the  
17 disclosure.

18 Q Okay.

19 A The only error he has is that I get \$600 an  
20 hour for court testimony and deposition. He has it only  
21 as 400. That's an important one to me.

22 Q So you've reviewed that expert disclosure  
23 pretty thoroughly, correct?

24 A Yes, sir.

Page 24

1 Q Okay, and did you meet with Mr. -- when did  
2 you have that meeting with Mr. Lundquist to review the  
3 expert disclosure?

4 A I believe it was in August. It's on my  
5 billing records. I can look at my bills.

6 Q And is that the only time you've met with  
7 Mr. Lundquist?

8 A Yes, sir. Well, yesterday, I met with  
9 Mr. Lundquist yesterday to discuss what I was going to  
10 bring.

11 Q And how long did you meet with Mr. Lundquist  
12 yesterday?

13 A We met for about four hours.

14 Q So the meeting in August that was three and a  
15 half hours, and your meeting yesterday that was four and  
16 a half hours, would be the sum total of the two meetings  
17 with Mr. Lundquist, correct?

18 A Yes, sir.

19 Q Has anybody met -- has anybody participated in  
20 those meetings with you and Mr. Lundquist?

21 A No.

22 Q It's just been you and him on it only?

23 A Yes, sir.

24 Q Other than with Mr. Lundquist, have you

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1 discussed this case with anybody?

2 A No, sir, nor would I think I would be  
3 permitted to do that. And by that I mean, by the  
4 protective order.

5 MR. HUTCHINSON: All right, so let's look at  
6 what we'll mark as Exhibit number 4.

7 (Whereupon, Exhibit 4 was marked for  
8 identification.)

9 BY MR. HUTCHINSON:

10 Q So Mr. Lundquist made an error on the amount  
11 per hour on Exhibit 4, and that should be \$600 per hour  
12 rather than 400, basically, is what you're saying? Is  
13 that correct?

14 A For court and deposition testimony. It's \$400  
15 an hour for work, that's correct, but it's for the other  
16 would be what you're paying today, I guess, is \$600 an  
17 hour.

18 Q Okay, well, let me make sure I understand.  
19 It's \$400 for your review of documents and records,  
20 correct?

21 A Yes, sir, when I stay in my office and just am  
22 working on my case.

23 Q And it's \$600 per hour when you're giving  
24 testimony at trial or in a deposition, correct?



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1 A Yes, sir.

2 Q Do you still have a standing \$6,000 per day  
3 amount for trial?

4 A For -- if I have to go to court, yes, sir.  
5 It's for 10 hours.

6 Q But it's \$6,000 per day regardless of how much  
7 time you spend?

8 A Yes, sir, if I'm in trial.

9 Q Do you charge any time for travel?

10 A I usually travel -- I believe my husband --  
11 I don't do the billing, but I believe we charge for the  
12 time in the airplane. If I was working on the plane,  
13 then we would charge the \$400, but if I'm just flying on  
14 the plane, I believe we charge 150 an hour.

15 Q What is the total amount of hours that you've  
16 spent on this case?

17 A Here, this is... (Deponent hands document to  
18 Mr. Hutchinson.)

19 Q You've handed me two invoices, one invoice  
20 Invoice number 2612 and Invoice 2639, and then a  
21 handwritten piece of paper that's all within the  
22 documents we've previously marked as an exhibit, is that  
23 correct?

24 A Yes, sir.

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1 strike that. What percentage of your income has been  
2 from working as an expert witness within the last five  
3 years?

4 A Um, about three years ago, I stopped doing  
5 that much medical device. Mainly I've been doing  
6 consulting or manufacturing consulting. So now it's  
7 completely litigation support. I'm trying to finish up  
8 the cases that I have. So it would be, a hundred  
9 percent right now is involved in litigation support.

10 Q And you've made over a million dollars over  
11 the last five years doing litigation work, correct?

12 A Yes, sir, and I've always been forthright with  
13 all my bills. So you have the total. I'm sure, in the  
14 records of all the depositions, you just put them all  
15 together.

16 Q Do you advertise your services anymore?

17 A No, sir.

18 Q You used to advertise on hugesettlements.com,  
19 didn't you?

20 A No, I didn't. Someone else put my website on  
21 there and brought it up in a trial. I forget which  
22 trial it was, I think a hormone replacement therapy  
23 case, they brought it up, and so then I quickly wrote to  
24 them to remove it. So no, I did not advertise on that

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1 Q And as best I can tell, you've spent nine and  
2 a half hours working on this case. Does that sound  
3 about right?

4 A Before, in getting ready for the prep, because  
5 the prep is more than that, going through all the  
6 documents.

7 Q Well, I'm looking at the invoices.

8 A Yeah, that's what I --

9 Q So tell me, based on the documents that you've  
10 brought with the deposition, how many total hours you've  
11 spent in this case from the point you were called  
12 initially to before you walked into this conference  
13 room.

14 A (Witness making handwritten calculations.)  
15 Thirty-six hours, when you take getting ready for the  
16 deposition.

17 Q I'm sorry?

18 A Thirty-six hours.

19 Q Okay, and how many hours do you anticipate  
20 spending after we leave today to get ready for trial?

21 A I don't know. I mean, I don't know if I'm  
22 going to be asked to do anything else. I haven't been  
23 asked to do anything else.

24 Q What percentage of your income is working --

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1 website.

2 Q Has it been removed?

3 A Last I've looked at it, it did, but it's  
4 really buried in there. It was, like, you had to know  
5 where to look. It's primarily an attorneys' website.  
6 It has an awful name, but it's an attorneys' website and  
7 so it was really cumbersome to find in the first place,  
8 but it came up in a trial and I quickly removed it.

9 Q Have you ever spoken with Dr. Miklos or  
10 Dr. Trepeta?

11 A No, sir.

12 (Whereupon, Exhibit 5 was marked for  
13 identification.)

14 BY MR. HUTCHINSON:

15 Q I've handed you what was marked as  
16 Exhibit 5 -- this is off the record.

17 (Discussion off the record.)

18 BY MR. HUTCHINSON:

19 Q Does this appear to be the reliance list for  
20 you for this case?

21 A Yes, sir.

22 Q And is this up to date?

23 A It should be, yes, sir.

24 Q And did you prepare this document?

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1 A I helped prepare the document.

2 Q Who prepared the document?

3 A Mr. Lundquist's firm prepared it, but we took  
4 it from my documents and from things that I've written  
5 for other things, and then I looked at the documents and  
6 I tried to determine if it was complete. So I was  
7 assisted, but I didn't do the secretarial work.

8 Q Is the time that you spent on this reliance  
9 list reflected in the total amount of time you spent in  
10 this case?

11 A No, sir.

12 Q Well, I'm sorry, we're going to need to get  
13 back, because my impression was that you spent 36 hours  
14 total working in this case.

15 A Working on the case, yes, sir.

16 Q Okay, but that doesn't include the time you  
17 spent on this reliance list?

18 A I didn't spend that much time on it. If  
19 I spend less than a half an hour, I don't bill. So  
20 there are times when I could do something very quickly  
21 and I don't bill, so the time is not there; and then  
22 they would e-mail me something and I'd look at it and  
23 I'd say, no, we need to add this, or --

24 Q Fair to say that you've spent less than -- or

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1 received from plaintiff's counsel were selected by he or  
2 his firm?

3 A No.

4 Q Okay. Did you make any efforts to get any  
5 other documents to rely on to support your opinions?

6 A Well, yeah, the reliance list has a lot of  
7 documents that I've got.

8 Q Such as...?

9 A The ones that aren't ETH.MESH in my documents  
10 that I've obtained, primarily.

11 Q Did you review any company documents that  
12 expressed or provided any evidence contrary to your  
13 opinions in this case?

14 A No.

15 Q Have you -- let's talk about your opinions for  
16 a minute.

17 A Yes, sir.

18 Q Have you published any of the opinions that  
19 you're offering today?

20 A Published? Anywhere -- you mean publicly?

21 Q Yes, ma'am.

22 A No. No, sir.

23 Q And I believe we already established that  
24 you've not tested -- done any testing of mesh or any

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1 a half an hour or less on this reliance list?

2 A Yes, sir. I mean, it would be a poor use of  
3 my time to be working on that list, but to assist is a  
4 good use.

5 Q What percentage of the materials on this  
6 reliance list were supplied by plaintiffs' counsel?

7 A Well, everything with Ethicon mesh has to come  
8 from the plaintiff's counsel. Some of these documents  
9 are available, so I would have obtained them, like the  
10 guidance documents, the FDA public notes, these are all  
11 available information from the FDA. So all the FDA  
12 documents were documents that I've -- I obtained, at  
13 various different times. So those are all publicly  
14 available. So the good majority of it came from me,  
15 basically.

16 Q And I haven't had a chance to look at these  
17 black notebooks yet, but are all of these ETH.MESH  
18 documents in these two black notebooks?

19 A The ones that I've relied on should be, yes,  
20 sir.

21 Q Okay. Did you ever ask plaintiff's counsel to  
22 get you more documents?

23 A Not for this case, no, sir.

24 Q Do you know how the documents that you

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1 type of mesh product.

2 A Correct, hands-on testing, that's correct.

3 Q And how do you define hands-on testing?

4 A Actually treating a patient or also looking at  
5 a mesh in a laboratory, looking at histology, working up  
6 mesh issues for Prolene. So I haven't done anything  
7 like that. The FDA doesn't do that, and so that's not  
8 the process I learned in the FDA.

9 Q What about any benchtop testing? Have you  
10 ever done any benchtop testing?

11 A Not on mesh. I've done benchtop testing, but  
12 not for mesh.

13 Q Okay. Did you do any type of tests whatsoever  
14 in this case that would be reproducible?

15 A I didn't do any testing.

16 Q Have you ever spoken with any scientist,  
17 engineer or medical doctor about your opinions?

18 A No, sir.

19 Q Have you ever spoken to anyone from the FDA  
20 about your opinions?

21 A No, sir.

22 Q Have you ever called or written or contacted  
23 FDA about any of your opinions?

24 A No, sir.

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1 Q Is it fair to say that all the opinions you  
2 have in this case are for litigation and not for any  
3 research or study?

4 MR. LUNDQUIST: Objection, form.

5 THE WITNESS: At this point in time, that's  
6 correct.

7 BY MR. HUTCHINSON:

8 Q Okay. Are you intending to offer any  
9 criticisms of FDA as part of your opinions at trial?

10 A No, sir.

11 Q Why not?

12 A They're working within the framework in which  
13 they can work. So no, the issue isn't the FDA. The  
14 FDA -- from what I understand, the issue is Ethicon.

15 MR. HUTCHINSON: Move to strike as  
16 nonresponsive.

17 Q Do you have any opinions -- scratch that.  
18 Are you offering any opinions to a reasonable  
19 degree of medical certainty about Ms. Garcia's medical  
20 condition?

21 A No, that would be cause- -- that's what  
22 I would see as causation. Obviously, I think that this  
23 device plays into her, but in terms of her physical --  
24 I haven't looked at her records to come up with a

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1 THE WITNESS: Well, I wouldn't say that.

2 I would say that I'm not a causation person that would  
3 be a physician talking about her specific case.

4 Obviously, if I'm sitting here discussing Ethicon and  
5 TVT Secur, then from a health risk assessment, I believe  
6 it's associated with her complications and her outcome.

7 So I don't know what you would call that in  
8 terms of legal term, but it's not primary causation, but  
9 is association. It's related in some way to her medical  
10 history in terms of her timing.

11 BY MR. HUTCHINSON:

12 Q No primary causation opinions about  
13 Ms. Garcia, correct?

14 A I believe that's what we're talking about.  
15 That would be for the physicians like Dr. Miklos and the  
16 treating physicians to talk about, but obviously,  
17 I think there's an association with her symptoms and the  
18 types of symptoms that are seen for these devices.

19 Q Understand. Let me ask you again, so we can  
20 have a clear record: You have no primary causation  
21 opinions about Ms. Garcia, correct?

22 MR. LUNDQUIST: Object to form.

23 THE WITNESS: Am I correct that primary  
24 causation would be the medical physician treating the

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1 causation opinion. I believe that would be to a  
2 treating physician.

3 Q It would be outside of your area of expertise?

4 A Well, no, it wouldn't be outside my area of  
5 expertise, but it's not what I see as my role. I'm  
6 trying to focus it as an FDA regulatory medical officer.

7 Q Why do you think that would be within your  
8 area of expertise, to offer a causation opinion?

9 A Because I did it at the FDA in terms of health  
10 risk assessment, in 21 C.F.R. Part 7. So I did that,  
11 and you would come up with issues and look for safety  
12 issues, but that's not my role in this particular case.

13 Q Let's talk about your opinions for a minute.

14 A And can I clarify?

15 Q Sure.

16 A I'm assuming you're asking about standard of  
17 care and her treatment and her outcome, and those to me  
18 are clinical, and that's why I will defer that to  
19 someone who's actually involved with her clinical care  
20 and evaluation.

21 Q Okay, but for the record, you have no opinions  
22 to a reasonable degree of medical certainty about what  
23 may have caused Ms. Garcia's alleged injuries, correct?

24 MR. LUNDQUIST: Object to form.

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1 patient and standard of care? That's not my area of  
2 expertise in this particular litigation.

3 BY MR. LUNDQUIST:

4 Q And you have no opinions -- primary causation  
5 opinions about what may have caused Ms. Garcia's alleged  
6 injuries, correct?

7 MR. LUNDQUIST: Object to form.

8 THE WITNESS: Well, that's -- in terms of a  
9 health risk assessment, I believe that the vaginal mesh  
10 is associated, and I don't know what you would call that  
11 in terms of legal -- I believe it's associated.

12 BY MR. LUNDQUIST:

13 Q Let's talk about the opinions you intend to  
14 offer at trial, okay?

15 A Okay.

16 Q Tell me, in general, what opinions that you  
17 plan on offering at trial.

18 A Well, shall we go to my disclosure?

19 Q You know, that might be a good idea. Let me  
20 get it. You're looking at Exhibit 4, correct?

21 A Yes, sir, and it would be specifically  
22 page 10.

23 Q Okay, I'm sorry, I'm on page 9.

24 A Well, 9 is my history. You want to go to 9?

<p style="text-align: right;">Page 38</p> <p>1 We can go to 9.</p> <p>2 Q Well, that's where it starts, isn't it?</p> <p>3 A Yes, sir, but it's really basically background</p> <p>4 there.</p> <p>5 Q Okay, but everything about Parisian on pages 9</p> <p>6 through the top of page 14, correct?</p> <p>7 A Yes, sir.</p> <p>8 Q And does this expert disclosure list all of</p> <p>9 the opinions that you plan on offering at trial?</p> <p>10 MR. LUNDQUIST: Form.</p> <p>11 THE WITNESS: The disclosure plus the</p> <p>12 discussion today in the deposition, because the</p> <p>13 disclosure's limited as to what it can say, and so my</p> <p>14 purpose, I believe, for the deposition is that you get</p> <p>15 to explore what those opinions are that are being listed</p> <p>16 here in the -- whatever this is called -- in the</p> <p>17 disclosure. Am I correct?</p> <p>18 BY MR. HUTCHINSON:</p> <p>19 Q Let's look at -- tell me the best way to boil</p> <p>20 down those four pages of opinions. So how would you, as</p> <p>21 a purported expert in this case, boil down your opinions</p> <p>22 from pages 9 to 13?</p> <p>23 MR. LUNDQUIST: Form.</p> <p>24 THE WITNESS: Well, the opinions begin where</p>	<p style="text-align: right;">Page 40</p> <p>1 A Yes, sir.</p> <p>2 Q All right. Let's look at page 9. It states</p> <p>3 in the middle, "Dr. Parisian presided over 162 health</p> <p>4 risk assessments."</p> <p>5 A Actually, it was more than that. It was when</p> <p>6 I was in the Office of Health Affairs, and then I did a</p> <p>7 hundred more when I was in ODE, so it's 262.</p> <p>8 Q For what purpose was that?</p> <p>9 A Pardon.?</p> <p>10 Q For what purpose was that?</p> <p>11 A It was to look at health risk assessments,</p> <p>12 like I was describing before, about what was the cause;</p> <p>13 to make recommendations to the FDA in terms of actions</p> <p>14 to take to protect the public. Many of them were</p> <p>15 voluntarily recalls, some of them are mandatory recalls.</p> <p>16 So it would be the processes described in 21 C.F.R.</p> <p>17 Part 7, health hazard, health risk assessments.</p> <p>18 Q And did you do any health risk assessments for</p> <p>19 mesh?</p> <p>20 A You know, I don't know. I don't recall.</p> <p>21 Q Do you recall doing any health risk</p> <p>22 assessments for any SUI product?</p> <p>23 A I don't recall -- these are post-market</p> <p>24 issues, these are products that are already being</p>
<p style="text-align: right;">Page 39</p> <p>1 it says, on page 10, after "Since leaving the FDA...",</p> <p>2 the next paragraph, "Dr. Parisian will testify that her</p> <p>3 opinions...", and so we can begin there, because the</p> <p>4 beginning is my history. You can ask me questions about</p> <p>5 my history. That's what before that paragraph.</p> <p>6 Do you have questions before that, or...?</p> <p>7 BY MR. HUTCHINSON:</p> <p>8 Q Let's look at -- let's look at page 9.</p> <p>9 A Okay.</p> <p>10 Q Well, before we do that --</p> <p>11 A Because this is your chance to explore my</p> <p>12 history.</p> <p>13 Q Thank you, and before we do that, if -- would</p> <p>14 it be fair that if I ask you questions about pages 9</p> <p>15 through 14 of this expert designation, and when we get</p> <p>16 to the end of page 14, will we have covered all of your</p> <p>17 opinions in this case?</p> <p>18 A I believe those would be the opinions that I'm</p> <p>19 planning to give in terms of the court. That's why</p> <p>20 I worked with Mr. Lundquist to try and make sure you had</p> <p>21 those opinions, but there's going to be more information</p> <p>22 and support provided in today's discussion.</p> <p>23 Q I understand, but this document would have all</p> <p>24 the -- your general opinions, correct?</p>	<p style="text-align: right;">Page 41</p> <p>1 marketed, and I don't recall specifically, but it was a</p> <p>2 while ago. I mean, the last time I was there it was in</p> <p>3 '95, so out of 262, I don't remember.</p> <p>4 Q It states, on the bottom of page 9, you were</p> <p>5 the FDA's liaison with the National Institutes of</p> <p>6 Health, involving what?</p> <p>7 A For those issues, ENT, ears, nose and throat</p> <p>8 surgery, kidney, pulmonary, women's health and</p> <p>9 alternative medicine. So I was -- had to be the person</p> <p>10 that would go to meetings with the NIH to discuss those</p> <p>11 issues.</p> <p>12 Q The NIH is a very respectable organization,</p> <p>13 correct?</p> <p>14 A Yeah, National Institutes of Health, yes, sir.</p> <p>15 Q It's one of the leading authorities in the</p> <p>16 field?</p> <p>17 A It is -- it is, in terms of this country, yes,</p> <p>18 sir. And in what field? I mean, it is an outstanding</p> <p>19 medical institution, that's all. I mean, it's... I'm</p> <p>20 not going to say anything bad about the NIH.</p> <p>21 Q When you were the liaison with the NIH, did</p> <p>22 you work with them on anything about mesh?</p> <p>23 A Not specifically about mesh.</p> <p>24 Q Anything about SUI?</p>

<p style="text-align: right;">Page 42</p> <p>1 A I don't recall that I did.</p> <p>2 Q Anything about the pelvic floor?</p> <p>3 A I don't recall that I did, but I don't recall</p> <p>4 that I didn't, because about that time there was</p> <p>5 interest by the NIH on pelvic floor and there was a</p> <p>6 document that was put out, and I don't recall, because</p> <p>7 the issue was that I was handling devices for women in</p> <p>8 terms of medical devices, and so I know that pelvic mesh</p> <p>9 and pelvic surgery was an issue, and I don't recall what</p> <p>10 happened with the NIH.</p> <p>11 Q Let's look on page 10.</p> <p>12 A Yes, sir.</p> <p>13 Q It states, in the middle,</p> <p>14 "During her tenure at FDA, Dr. Parisian</p> <p>15 reviewed hundreds of marketing applications</p> <p>16 for safety and efficacy."</p> <p>17 Correct?</p> <p>18 A Yes, sir.</p> <p>19 Q Those are the 510(k)'s that you reviewed?</p> <p>20 A It would be 510(k)'s and PMAs, and then also</p> <p>21 the investigational device associated clinical trials.</p> <p>22 Q Did any of the 510(k)'s that you reviewed have</p> <p>23 long-term clinical data?</p> <p>24 A Yes. The company would commit to follow up,</p>	<p style="text-align: right;">Page 44</p> <p>1 reviewed recommend -- strike that.</p> <p>2 Did any of the 510(k) applications that you</p> <p>3 reviewed have any labeling that says there was no</p> <p>4 long-term clinical data?</p> <p>5 A Well, there would be nothing that would</p> <p>6 prevent any 510(k) manufacturer from putting that on.</p> <p>7 If a device was particularly dangerous -- and I'm trying</p> <p>8 to think. We had devices that were 510(k)'s because</p> <p>9 510(k)'s would cover implanted devices. We would have</p> <p>10 some kind of statements like that, if there was no</p> <p>11 long-term data known, because it usually would be a risk</p> <p>12 versus benefit, that that would be a device, like I can</p> <p>13 think of devices for, like, handicapped children or</p> <p>14 something that would be the unknown, that they would</p> <p>15 have something like that. So there's nothing that</p> <p>16 prevents that statement, but it's usually a riskier</p> <p>17 device.</p> <p>18 Q All right. Let's go back to my question,</p> <p>19 okay?</p> <p>20 A Okay.</p> <p>21 Q Did you review any 510(k)'s that had any</p> <p>22 labeling, proposed labeling, that says there was no</p> <p>23 long-term clinical data?</p> <p>24 MR. LUNDQUIST: Form.</p>
<p style="text-align: right;">Page 43</p> <p>1 because they would make claim on the long-term follow-up</p> <p>2 data. So for industry to make comparative claims, they</p> <p>3 would come in and say, well, we've done this study, so</p> <p>4 yes.</p> <p>5 Q You've never reviewed a 510(k) for any type of</p> <p>6 mesh product, have you?</p> <p>7 A I don't know, because it's used throughout</p> <p>8 surgical stuff. So I don't -- I don't remember because</p> <p>9 I did surgical devices, so I don't -- I did do mesh.</p> <p>10 I was involved with abdominal adhesions devices that was</p> <p>11 Proceed, that was Ethicon's product. So I was involved</p> <p>12 with mesh issues.</p> <p>13 Q Okay. Let's talk about mesh for the pelvic</p> <p>14 floor. You've never reviewed a 510(k) for mesh for</p> <p>15 pelvic floor, correct?</p> <p>16 A Not that I'm aware of.</p> <p>17 Q Or SUL.</p> <p>18 A Yes, that's correct, because a lot of times,</p> <p>19 they were using -- at the period of time I was there,</p> <p>20 they were doing fascia. So I was aware of urological</p> <p>21 issues, but with primarily with fascia, and they were</p> <p>22 also doing the sacrocolpoplexy sling and bone anchor, so</p> <p>23 I don't believe mesh was being used.</p> <p>24 Q Did any of the 510(k) applications that you</p>	<p style="text-align: right;">Page 45</p> <p>1 THE WITNESS: Well, for 510(k), sure, because</p> <p>2 you don't even have to be cleared -- you don't even have</p> <p>3 to be making a device to get a 510(k) cleared.</p> <p>4 So if it was a risky device, that information</p> <p>5 would be included in terms of the risk versus benefit</p> <p>6 for physicians. I don't remember a specific device, but</p> <p>7 would that be unusual? No, I don't think it would be</p> <p>8 unusual, particularly if there was no history for the</p> <p>9 device. But again, it would typically be a risky</p> <p>10 device.</p> <p>11 BY MR. HUTCHINSON:</p> <p>12 Q Down there on the bottom, it said, on page 10,</p> <p>13 it says,</p> <p>14 "Dr. Parisian will provide her opinions</p> <p>15 on the FDA's clearance of TVT-S on</p> <p>16 November 28, 2005, including concerns with</p> <p>17 Ethicon's design validation process."</p> <p>18 Do you see that?</p> <p>19 A Yes, sir.</p> <p>20 Q What concerns do you have about the design</p> <p>21 validation process?</p> <p>22 A It's internal concerns by Ethicon. There's --</p> <p>23 and I have marked some tabs where they discuss it. If</p> <p>24 you look at this book, the first book, which we'll call</p>

<p style="text-align: right;">Page 46</p> <p>1 this one Volume 1, this one that says "TVT Secur," there  2 is a series of documents in here talking about the  3 concerns with quality assurance and the validation  4 process, design protocols. And so there's internal  5 e-mails.</p> <p>6 It would begin with tab 8, 9, 10, 11, 12, 13,  7 14, 15, 16, 17, 18. So the tabs that I -- in this  8 Volume 1 book describe internally that the company was  9 concerned, particularly their quality assurance people,  10 with the adequacy of the design validation protocol for  11 the TVT Secur device, and that it wouldn't live up to  12 the scrutiny of the FDA if they came in and inspected  13 because of the way it had been done. There were several  14 series of amendments that were made to the design  15 validation. So I'd direct you to those documents, in  16 terms of TVT Secur.</p> <p>17 I think what's even more important in that  18 opinion, there, is that I see that, as an FDA regulatory  19 person, my role is to explain the history of how the  20 510(k) -- to go step back, to explain to a jury the  21 510(k) process and what it requires, what a  22 manufacturer's required.</p> <p>23 So I believe that's usually what -- so you  24 skipped over that part, but I think that's what I would</p>	<p style="text-align: right;">Page 48</p> <p>1 design -- before a device is released, and so those  2 would be things that, in terms of good manufacturing,  3 are of concern.</p> <p>4 Like, they actually did one design validation  5 where they gave the questionnaires of studies to  6 doctors -- and that would be in tab 11, it would be  7 dated January 26 -- January 3rd, 2006 -- and the  8 doctors' response, when they saw the original study  9 questionnaire, was that they wanted them to revise the  10 IFU.</p> <p>11 So even before they had released the product,  12 of the physicians who were looking at this, the product  13 and the performance of the product as part of Ethicon's  14 design validation, were raising questions about the  15 adequacy of the Instructions For Use for doctors.</p> <p>16 Q Dr. Parisian, do you know what the design  17 requirements are?  18 A Sure.  19 Q The requirements for design validation?  20 A Sure. In terms of the FDA? In terms of 21  21 C.F.R. 820? Sure, you have to ensure that your company  22 is making a product that will fulfill user needs, and  23 you have to address any potential risks in terms of the  24 performance of that product, because it's a prohibited</p>
<p style="text-align: right;">Page 47</p> <p>1 be giving to a jury is explaining the FDA process and  2 then putting the TVT Secur into that context, of  3 framework.</p> <p>4 Q The concerns -- but the concerns that are  5 referenced in this disclosure are concerns that you said  6 you read from company documents, correct?  7 A Um, the internal concern has to come from the  8 company documents, because --  9 Q Well --  10 A -- because this would be privileged  11 information. It wouldn't be out in the real world.</p> <p>12 Q Well, I want to know what -- I want to know  13 your opinions about Ethicon's design validation process.</p> <p>14 A Well, one that the quality assurance personnel  15 were concerned about, that the company was trying to  16 rush this product to market and they hadn't done  17 adequate testing. They hadn't done design validation,  18 which is a key to a successful device, is that the  19 company, under 21 C.F.R. 820, must do adequate design  20 validation to make sure that the device performs as  21 needed for the patient and the physician.</p> <p>22 And so it's a red flag, in a way, when the  23 quality assurance people are concerned about the quality  24 of the design validation that was done before a</p>	<p style="text-align: right;">Page 49</p> <p>1 act for you, Ethicon, to market a device that's not safe  2 and effective.</p> <p>3 Q On the bottom of page 10 it states,  4 "Ethicon relied upon two of their own  5 devices, the TVT and TVT-O, as substantial  6 equivalent predicate devices, despite obvious  7 differences between them."  8 Do you see that?  9 A Yes, sir.</p> <p>10 Q What are the obvious differences between them?  11 A Um, the obvious differences in them -- well,  12 the length of the mesh, the insertion --  13 Q The length of mesh between TVT and TVT-O?  14 A Yes, sir. Okay, because -- and also, well,  15 TVT is a retro-pubic insertion, makes a U-shaped sling,  16 whereas TVT-O is an H-shaped sling, and so both of them  17 had a process where you would have two points of  18 fixation in terms of putting in your sling, yes.</p> <p>19 Q What other differences between --  20 A Well, and so now the company was introducing  21 what they called a single-incision sling, SIS, that  22 had -- was much shorter. It was only 8 centimeters  23 long. So you changed the lengths of the sling.  24 You had a new insertion device, in terms of,</p>



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1 that had never been used for the TVT or the TVT-O.  
 2 You had a new insertion row, in terms of also  
 3 having to tension this device, because neither TVT or  
 4 TVT-O required tensioning. So that was a new issue.  
 5 So you had a new inserter, you had new  
 6 tensioning, you had a new release mechanism, you had --  
 7 the Ethisorb's fixation was different than had been done  
 8 with either one of those devices.  
 9 So the only thing that's similar is that there  
 10 was Prolene, but even the Prolene was different, in that  
 11 the Prolene for TVT and TVT-O was a mechanical-cut  
 12 Prolene, as opposed to the introduction of a laser-cut  
 13 Prolene for TVT-S, which changes the stretchability of  
 14 the Prolene. So there were a lot of differences.  
 15 Q Do you know how the stretchability of  
 16 mechanically-cut versus laser-cut mesh has changed the  
 17 physiological range?  
 18 A The physiological range --  
 19 Q The --  
 20 A No, no, no --  
 21 Q I'm asking --  
 22 A Yes, I do know the answer to that --  
 23 Q Okay, can you explain that, please?  
 24 A -- but I want to explain, the word

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1 "physiological range" came from the company, and it was  
 2 introduced by the company --  
 3 Q Dr. Parisian --  
 4 A No, no, no, let me explain.  
 5 Q I'll move to strike as nonresponsive.  
 6 A No, it was -- yes, I do know the difference.  
 7 Q All right, I'm not sure -- okay, then  
 8 explain --  
 9 MR. LUNDQUIST: Let her finish her answer.  
 10 BY MR. HUTCHINSON:  
 11 Q I'm not asking where the name "physiological  
 12 range" came from.  
 13 A No, it's --  
 14 Q What I'm asking is, do you know --  
 15 A Yes, I do know the difference.  
 16 Q Okay, what's the difference?  
 17 A The difference is, the physiological range was  
 18 to cover the range of the change in stretchability. The  
 19 mechanical-cut was -- had more stretch, was more elastic  
 20 than the laser-cut mesh, and so in order to be able to  
 21 reference the seven years of history with the TVT and  
 22 the TVT-O, the company created the term "physiological  
 23 range," even though they knew that the Prolene stretch  
 24 had changed. They expanded the standard for what would

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1 be the acceptable stretch, to include the TVT Secur.  
 2 So it was a term introduced by the company to  
 3 just cover that we had totally changed the  
 4 stretchability, we had made it a much stiffer mesh, but  
 5 that term allowed the company internally, in their  
 6 documents, to then say, well, now we can recite -- we  
 7 can use the years of the TVT, but the mesh was totally  
 8 changed, because you had -- laser-cut edging changes the  
 9 edge, it melts it, so that you have a much rougher edge  
 10 than you did for TVT and.... So yes, I do know the  
 11 difference.  
 12 Q Dr. Parisian, are all of the documents that  
 13 you relied on in support of any opinion about  
 14 mechanically-cut versus laser-cut within the documents  
 15 we've already marked as Exhibit 3, or -- 2, rather?  
 16 A The one specific for what I'm talking about  
 17 the physiological range in Ethicon, yes, that's in  
 18 there --  
 19 Q But --  
 20 A -- in terms of -- but the issue is, I've dealt  
 21 with Prolene mesh before, and I know what a laser-cut  
 22 does versus mechanical-cut, but the documents that would  
 23 be specifically supporting my opinions about laser-cut  
 24 are in here.

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1 Q Did you ever review any clinical expert report  
 2 regarding mechanically-cut and laser-cut mesh and the  
 3 responses to that?  
 4 A No.  
 5 Q Okay. Let's look at the top of page 11.  
 6 MR. HUTCHINSON: Off the record for a second.  
 7 (Discussion off the record.)  
 8 BY MR. HUTCHINSON:  
 9 Q It states at the top of page 11 on Exhibit 4,  
 10 "Dr. Parisian will opine on potential flaws of the  
 11 design of the TVT-S." Do you see that?  
 12 A Yes, sir.  
 13 Q What is -- what are the potential flaws of  
 14 design of the TVT Secur?  
 15 A Okay. The potential flaws would be the use of  
 16 the Ethisorb Dura Patch in terms of the attachment end,  
 17 because that's not -- that's -- and we can talk about  
 18 why I think that's -- but just to go through my list.  
 19 The other one would be the change in the mesh,  
 20 the stretchability, in terms of decreasing it.  
 21 Q You're talking about laser-cut versus  
 22 mechanical-cut?  
 23 A Yeah, that would be one aspect of it. So we  
 24 have fixation, poor fixation with the Ethisorb. We have



<p style="text-align: right;">Page 54</p> <p>1 the change in the mesh in terms of the laser cut. We</p> <p>2 have the tensioning, that the tensioning mechanism is --</p> <p>3 has been a major issue in terms of the safety of this</p> <p>4 device. So there weren't development of instructions on</p> <p>5 appropriate tensioning.</p> <p>6 Let's see, what else? The -- in terms of, the</p> <p>7 complaints that were being received originally were the</p> <p>8 inserter was sharp and could cut things, you know, cut</p> <p>9 organs and cause damage, and then the release mechanism</p> <p>10 was problematic in terms of the physician knowing</p> <p>11 exactly where they were releasing. Not only is</p> <p>12 tensioning hard, but releasing. The physicians and</p> <p>13 their key opinion leaders said they have a difficult</p> <p>14 time knowing where they're putting the mesh.</p> <p>15 Q Anything else?</p> <p>16 A Let's see. 8 centimeters. I think the</p> <p>17 8 centimeters, when they go into the design of the next</p> <p>18 generation mesh, I believe they're doing that around</p> <p>19 2008, they're talking about going with a longer mesh</p> <p>20 because they kind of arbitrarily chose the 8 centimeters</p> <p>21 based on that it may be acceptable for most bodies, and</p> <p>22 so --</p> <p>23 Q Anything else?</p> <p>24 A I'm thinking. Those are the designs. I think</p>	<p style="text-align: right;">Page 56</p> <p>1 safety and effectiveness that are not addressed, and</p> <p>2 they got clearance, but once the product gets cleared,</p> <p>3 they are not addressing safety issues in terms of doing</p> <p>4 a CAPA and creating preventive types of issues,</p> <p>5 corrective and preventive issues.</p> <p>6 Let's see, what else? And that's not</p> <p>7 discussing the IFU, because internally there was a</p> <p>8 discussion that they needed to create a better</p> <p>9 instructions for the physicians in terms of a cookbook</p> <p>10 as opposed to the IFU. The IFU doesn't have the same</p> <p>11 issues that were known in terms of the CER that was</p> <p>12 written by a Dr. Owens, in terms of a potential risk.</p> <p>13 None of that information was being provided to the</p> <p>14 physicians. But that's post-market, so we'll leave</p> <p>15 that. But the CER was actually pre-market. So they</p> <p>16 knew those risks and they did not plan to provide those</p> <p>17 to the physician.</p> <p>18 Q Any other flaws of the design of the TVT-S?</p> <p>19 A Let me look at tab 8. (Witness reviewing</p> <p>20 documents.) I talked about the Ethisorb, which is your</p> <p>21 fleece, and we talked about the stretch in terms of the</p> <p>22 mesh, we talked about that.</p> <p>23 They also changed -- the pull-out force was</p> <p>24 changed to 164 grams, which was the physiological limit.</p>
<p style="text-align: right;">Page 55</p> <p>1 that the reproducibility is an issue with the design,</p> <p>2 poor design, in that even the key opinion leaders are</p> <p>3 saying that they were having a hard time predicting what</p> <p>4 the outcome would be.</p> <p>5 So that's an issue with the design, that you</p> <p>6 want to make sure that it can be used consistently by</p> <p>7 the physicians if they do it right, and by your</p> <p>8 instructions, that they will have a good outcome, and so</p> <p>9 that's a flaw.</p> <p>10 Let's see, what else was there? The sheep</p> <p>11 study. I think the sheep study was a problem. When you</p> <p>12 go through the sheep study, you realize that they don't</p> <p>13 do a sheep study simulating use of the product in even</p> <p>14 the sheep. They do flat pieces of mesh in terms of</p> <p>15 adhesion, in terms of ability to attach the mesh to the</p> <p>16 wall with the Ethisorb. They don't simulate a real use</p> <p>17 situation and the forces of the pelvis.</p> <p>18 Let's see, what else? So animal testing would</p> <p>19 be an issue.</p> <p>20 Another issue is that they didn't do a</p> <p>21 comparison of testing of the TVT and the TVT-O to the</p> <p>22 TVT-S, and so they're saying that they're substantial</p> <p>23 equivalent, they get cleared to make a product that's a</p> <p>24 substantial equivalent, and yet there are issues of</p>	<p style="text-align: right;">Page 57</p> <p>1 They made that change for the TVT-S. Originally, the</p> <p>2 pull-out force had been around 500 grams. So this is</p> <p>3 coming from my tab 18, and it's going through the design</p> <p>4 history of the TVT Secur.</p> <p>5 Another issue is that they marketed both the</p> <p>6 retropubic U and the obturator H as being able to be</p> <p>7 done with the same device, and that -- that is like,</p> <p>8 really? You really need to test that out, because</p> <p>9 you're talking about physicians' ability to plant two</p> <p>10 different devices, that you supposedly can do it with</p> <p>11 this device, and I think that -- and that's how they</p> <p>12 marketed it, and I think even in retrospect, they saw</p> <p>13 that that was a bad thing to do.</p> <p>14 And they say that the placement of this thing</p> <p>15 is even more -- in this presentation, is even more</p> <p>16 critical than when you place the TVT, because if you</p> <p>17 don't plant -- if you don't place it next to the pelvic</p> <p>18 bone, the pubic bone, you're going to hit the bowel. So</p> <p>19 you have an issue of potential bowel perforation. You</p> <p>20 also have an issue with bladder perforation. There was</p> <p>21 more bladder perforation, so that also is a poor design.</p> <p>22 And also, the other products had all been sold</p> <p>23 as tension-free. So this was now adding tension to the</p> <p>24 whole mix. I think I talked about tensioning, didn't I?</p>

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1 Q Have we discussed all the potential flaws that  
2 you believe were in the design of the TVT-S?

3 A That's what I'm trying to do. I'm trying to  
4 make sure. So we knew -- I had mentioned the  
5 8 centimeters, I mentioned the fixation, I mentioned the  
6 correct -- that you need to have the correct placement,  
7 and yet, in -- okay, so that's not design. What else?

8 The versatility; we talked about the sheep  
9 study. Okay, those would be things that, before you put  
10 a product on the market, should have been addressed.

11 Q Dr. Parisian, have we talked about all your  
12 opinions about the potential flaws of the design of the  
13 TVT-S?

14 A Well, the other big flaw is they didn't do a  
15 clinical trial. The pre-market release that they did  
16 with Dr. Artibani and Dr. Nilsson came up with safety  
17 issues, and the company was going to proceed ahead with  
18 the clinical trials, and I think Dr. Weisberg, in his  
19 CER, said that they were not going to do a clinical  
20 trial based on it being like the TVT and the TVT-O,  
21 where internally they're talking about it being  
22 different.

23 Q We'll add clinical trials to the list.  
24 Anything else?

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1 A What I'm doing in my answer is I'm generating  
2 as pre-market. These are pre-market flaws that you  
3 should have been able to see in terms of your risk  
4 assessment and your 21 C.F.R. 820, your design flaws.  
5 We're not talking about post-market. These are things  
6 that should have been known to an expert in this product  
7 before they put it on the market.

8 Q Have we talked about all potential design  
9 flaws in the TVT-S, in your opinion, pre-market?

10 A Well, the other was they relied on engineer  
11 Dan Smith, instead of the relying on their own internal  
12 physicians, as potential risk.

13 Q Okay, anything else?

14 A As for pre-market, yes.

15 Q Okay, thank you, and these opinions that you  
16 formed about the potential design flaws of the TVT-S,  
17 those are opinions are based on your review of Ethicon's  
18 documents, correct?

19 A Yes, sir.

20 Q Anything else?

21 A Well, I think the other thing that I didn't  
22 mention was the learning curve, that it actually -- the  
23 company was aware it was difficult for surgeons to put  
24 these in to be begin with, and that's a user error

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1 potential problem that you have to put into your design  
2 documents and your design validation, and that really  
3 wasn't adequately addressed, and when it was given to  
4 physicians, they said change the instructions, and they  
5 didn't. They kept the same instructions.

6 So I think, that it was going to be very  
7 difficult to put this product in was known before they  
8 even launched it in the United States.

9 Q Let's look at the -- all right. Anything  
10 else, Dr. Parisian?

11 A Um --

12 Q This is my one and only time to get all your  
13 opinions, and I'm entitled to them, so --

14 A I know, I'm trying --

15 Q -- I need to ask you. Anything else?

16 A I'm trying to answer. Well, they worked with  
17 Prolene for years, so they should have known about the  
18 potential for mesh degradation, that over time you could  
19 have mesh degradation. So that was something to also  
20 address, because this whole thing is based on the -- and  
21 I'm not the pathologist discussing this, but I'm the FDA  
22 person -- that the integration of the -- the implant, to  
23 hold it in place, is important.

24 Q Anything else, Dr. Parisian?

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1 A Okay, let me look, let me look. Well,  
2 I think --

3 Q And let me ask you this. What are you  
4 reviewing now?

5 A Here, you can see. (Witness indicating.)

6 Q You're reviewing your expert designation,  
7 correct?

8 A Yes, sir.

9 Q Okay.

10 A And I'm trying to kind of shorten it, so --

11 Q Sure, if you can shorten it so we can move on,  
12 I'd appreciate it. Anything else?

13 A The other issue I think that the company  
14 needed to take into consideration was that they were  
15 already marketing the TVT and the TVT-O, and so those  
16 devices actually had a potential risk for erosion; so  
17 the complications, dyspareunia, vaginal scarring. So  
18 there was a known risk associated with these types of  
19 device. They didn't just begin one day and make the TVT  
20 Secur. So those elements that were already known, if  
21 you're going to make a less-invasive, safer device,  
22 should have been addressed in their early testing and  
23 design, and they didn't.

24 Q Anything else?

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1 A Yeah. Before they even marketed this device,  
2 they did have the pre-market information from the  
3 physicians who had done it, and there was no plans to  
4 have a certification training to make sure that the  
5 doctors were aware of how to use this product.

6 Q And that's a potential design flaw with the  
7 design, correct?

8 A From the very beginning, that there was  
9 nothing put out that they were going to address it. As,  
10 like I said, they already had the history of the TVT,  
11 the TVT-O, so --

12 Q And any --

13 A -- insertions is important.

14 Q Move to strike as nonresponsive. Anything  
15 else, Dr. Parisian?

16 A I think that will do it.

17 Q Okay. Look at page -- at the top of page 11.

18 A Yes, sir.

19 Q It says,

20 "Dr. Parisian will also discuss the  
21 adequate and ethical disclosures required when  
22 ghostwriting articles."

23 Do you see that?

24 A Yes, sir.

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1 as a "thank you for helping."

2 Q Okay, anything -- would you give me another  
3 example?

4 A Well, and also, those would be under the  
5 regulations, in terms of writing adequate instructions  
6 and adequate warning, adequate information about the  
7 product. Where is this information coming from?

8 And so that's required, in terms of  
9 ghostwriting, that a company disclose that to a  
10 physician, and particularly if they're going to using it  
11 as their marketing information that they're going to  
12 have their sales reps give out, and so that would be  
13 under your 21 U.S.C. 352 and adequate instructions,  
14 adequate warnings.

15 It would also feed into --

16 Q Dr. Parisian, let's stick with answering the  
17 question.

18 MR. LUNDQUIST: She's answered your question  
19 about the ghostwriting.

20 MR. HUTCHINSON: I know. I'm asking, for  
21 example, she gave me the Artibani sheep study.

22 Q What other examples?

23 A All right, well, there's the performance  
24 evaluations of a new TVT-like mesh system for the

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1 Q What do you mean by that?

2 A Well, that in terms of, you have to -- well,  
3 I would specifically refer you to my book, in terms of  
4 tab 6 and tab 7. Do you want me to pull those out, in  
5 terms of ghostwriting?

6 Ghostwriting refers to -- let me get that, 6  
7 and 7.

8 Q I'm not asking about what ghostwriting refers  
9 to. What I'm asking is: What are your opinions about  
10 adequate and ethical disclosures required when  
11 ghostwriting? So if you can stick to that question, I'd  
12 appreciate it.

13 A All right, but for your benefit, I'll  
14 reference to you tab 6 and 7, when you have my book.

15 Ghostwriting ethical is disclosure. The  
16 company needs to inform the physician, or the patient,  
17 the source of the information that they're -- that  
18 they're providing.

19 They have to also disclose their involvement  
20 in writing a report. For example, the sheep study was  
21 put out, published, and Dr. Artibani says they hadn't  
22 been involved in it. He was basically put on the  
23 article as a name, and Dan Smith, who had actually done  
24 the sheep study involved at this time, was only put on

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1 treatment of stress urinary incontinence. It's in my  
2 tab 7, and it basically says, we need to get two  
3 surgeons as lead authors, otherwise there's a little  
4 credibility leak for customers.

5 So Ethicon is writing an article to be  
6 published about the use of the TVT mesh system for SUI,  
7 and they're including the TVT Secur -- they're saying  
8 how -- this is -- this example is for TVT, and they're  
9 proposing --

10 Q Okay. It's not for TVT Secur, correct?

11 A Well, that's correct, but the page says,  
12 "would suggest something like performance evaluation of  
13 this for TVT Secur."

14 So this is an example of the company writing  
15 an article, they say they're going to find doctors'  
16 names to put on the article, and they're talking about  
17 that they would like a similar type of article for TVT  
18 Secur.

19 So this is an example of ghostwriting, and  
20 this is an example where there's not a disclaimer that  
21 the company has written the article, and that the --  
22 they're just going to find doctors to put the names on.

23 Q Can you give me --

24 A That's ghostwriting.

<p style="text-align: right;">Page 66</p> <p>1 Q Excuse me. Can you give me any other</p> <p>2 examples?</p> <p>3 A Well, I gave you those two examples, talking</p> <p>4 internally.</p> <p>5 Q Well, can you give me any other examples?</p> <p>6 A Well, those are the two I have.</p> <p>7 Q Other than those two.</p> <p>8 A There is, I believe... (Witness reviewing</p> <p>9 documents.)</p> <p>10 Q And Dr. Parisian, just for the record, when</p> <p>11 I'm asking for examples, you're looking under tab 6</p> <p>12 and 7, correct?</p> <p>13 A I was. I'm looking right now at tab 4,</p> <p>14 because of the -- the plan for how they're going to</p> <p>15 release the product.</p> <p>16 Q Can you give me any other examples, other than</p> <p>17 the two that we've already discussed?</p> <p>18 A That's why I'm looking at this one document,</p> <p>19 to see if they talk about those -- getting publications</p> <p>20 out, but I don't -- I don't see that they do. So those</p> <p>21 were the two that I'll stick with.</p> <p>22 Q If you look on -- further on page 11 --</p> <p>23 A Um-hum.</p> <p>24 Q -- kind of in the middle, it states,</p>	<p style="text-align: right;">Page 68</p> <p>1 trials that they -- there wasn't a plan to do clinical</p> <p>2 trials before they launched, or to do a human trial, or</p> <p>3 even to do a sheep study that simulated the use.</p> <p>4 So that would be testing, as opposed to the</p> <p>5 flaws. The design flaws were the obvious issues that</p> <p>6 they needed to -- but even their testing was inadequate.</p> <p>7 So that's little bit more.</p> <p>8 Q Let talk about post-market. What do you</p> <p>9 believe -- what are your opinions as to what Ethicon</p> <p>10 failed to do on post-market of the TVT Secur?</p> <p>11 A Well, in terms of post-market, they weren't</p> <p>12 actually -- they didn't get any clinical data on the</p> <p>13 post-market failure. Most of these devices, when they</p> <p>14 failed, they were failing in 12 weeks.</p> <p>15 I went and did an MDR search, and that's not</p> <p>16 in here, but it was part of this type of an opinion, and</p> <p>17 Medical Device Reports are described under 21 C.F.R.</p> <p>18 803, and they're mandatory for Ethicon when they receive</p> <p>19 information about a failure of their device, return of</p> <p>20 SUI, erosion. Those would be failures.</p> <p>21 If you look at the MDRs, the Medical Device</p> <p>22 Reports, and you look at the reports that are being</p> <p>23 discussed internally about the failures, they're not</p> <p>24 consistent.</p>
<p style="text-align: right;">Page 67</p> <p>1 "Dr. Parisian will also testify that</p> <p>2 Ethicon failed to adequately study, design and</p> <p>3 test the TVT-S prior to allowing the device to</p> <p>4 be sold."</p> <p>5 Do you see that?</p> <p>6 A Yes, sir.</p> <p>7 Q Have we already discussed all of your opinions</p> <p>8 relating to the adequacy of studying, designing and</p> <p>9 testing the TVT Secur? I think so, but I just want to</p> <p>10 make sure.</p> <p>11 A That's the pre-market, but then it goes on to</p> <p>12 talk about the post-market.</p> <p>13 Q I understand, pre-market. Have we already</p> <p>14 discussed all of your opinions?</p> <p>15 A About the potential flaws of the design.</p> <p>16 Q Of the study, design and testing of the TVT</p> <p>17 Secur, in pre-market.</p> <p>18 MR. LUNDQUIST: Objection.</p> <p>19 THE WITNESS: If I divide it into pre-market,</p> <p>20 and then the next part of that paragraph --</p> <p>21 BY MR. HUTCHINSON:</p> <p>22 Q I'm sorry, is that a yes?</p> <p>23 A Let me think about it. Yes, I think that</p> <p>24 would be the -- well, the tests would be the clinical</p>	<p style="text-align: right;">Page 69</p> <p>1 I went and just, last night, quickly just put</p> <p>2 in "TVT Secur" -- if I can find that document --</p> <p>3 Q Well, why don't you stick with me. On</p> <p>4 post-marketing opinions --</p> <p>5 A Well --</p> <p>6 Q -- the first one is no clinical data, correct?</p> <p>7 A Well, yeah, this is essential to post-market,</p> <p>8 because this is --</p> <p>9 Q Okay.</p> <p>10 A -- mandatory.</p> <p>11 Q Are we on the second opinion?</p> <p>12 MR. LUNDQUIST: She's talking about her --</p> <p>13 she's still articulating her point on post-market</p> <p>14 issues, I think.</p> <p>15 THE WITNESS: Yes.</p> <p>16 BY MR. HUTCHINSON:</p> <p>17 Q All right, we're back.</p> <p>18 A Post-market requires -- when I say</p> <p>19 post-market, that would include complaint file handling,</p> <p>20 and this would be all described under 21 C.F.R. 820. It</p> <p>21 would be complaint file handling as well as medical</p> <p>22 device reporting.</p> <p>23 So internally, the documents, I see</p> <p>24 discussions of failures in Germany and Australia, and</p>

<p style="text-align: right;">Page 70</p> <p>1 that information is not being filed with the FDA, and it</p> <p>2 should be, because that information is not -- unless the</p> <p>3 company is feeling that they don't need to file because</p> <p>4 it's already in their labeling, okay, in their IFU.</p> <p>5 And so if you look at -- which it's not -- if</p> <p>6 you look at the trend -- okay, I did a really, really</p> <p>7 fast look at the Medical Device Reports last night,</p> <p>8 because this is a discussion about post-market, and</p> <p>9 I felt that I needed to look at the MDRs to see if the</p> <p>10 company was filing MDRs, because they're required to</p> <p>11 when they find out that the product failed.</p> <p>12 And when I looked at the years 2006 through</p> <p>13 2007, which is a year block, for Gynecare TVT, there</p> <p>14 were no reports in the FDA's database of anything, okay?</p> <p>15 So -- and that's all the TVT products. There's nothing.</p> <p>16 And then when I did a look at year -- on the</p> <p>17 back of this page, you may want to have -- be aware</p> <p>18 there's information on the back.</p> <p>19 Q This is handwritten notes by you, correct?</p> <p>20 A Yes, sir.</p> <p>21 Q And this is in what we've previously marked as</p> <p>22 Exhibit 2, correct?</p> <p>23 A Right, but it's on the back, so somebody may</p> <p>24 miss it.</p>	<p style="text-align: right;">Page 72</p> <p>1 from a user facility, not from the company.</p> <p>2 The year 2010 through 2011, there were nine</p> <p>3 reports, and I believe there was one report for Secur,</p> <p>4 where there was an erosion, and the company said it was</p> <p>5 because the doctor implanted it too tight for the Secur,</p> <p>6 and that the woman had had severe pain, on antibiotics</p> <p>7 for two years, numbness both legs, incontinence, and so</p> <p>8 that was reported to the company supposedly in 2010 for</p> <p>9 an implant of 2008.</p> <p>10 When you look at 2011 to 2012, there's 18</p> <p>11 reports, and the Secur report is actually voluntary,</p> <p>12 it's by somebody else, for an event from 6/1/2007, where</p> <p>13 a woman was complaining in one week post her surgery she</p> <p>14 was incontinent.</p> <p>15 Okay, and then you look at 2012 to 2013, and</p> <p>16 there are 22 records, of which five of them are Secur.</p> <p>17 So FDA is not getting a lot of MDR reports here from the</p> <p>18 company up through 2013.</p> <p>19 Then 2013 to 2014, after Ms. Garcia's</p> <p>20 procedure, there is over 500 records. I didn't look at</p> <p>21 all of them because it was late, but there were over 500</p> <p>22 records.</p> <p>23 So the FDA is not getting reports for anything</p> <p>24 for TVT really until the year 2013, and there were 61 of</p>
<p style="text-align: right;">Page 71</p> <p>1 Q We'll make sure we have it, and what is this?</p> <p>2 A This is -- so my computer wasn't working very</p> <p>3 well last night, so that's why I didn't print it all</p> <p>4 out, but I went and I looked at the years 2007 to 2008,</p> <p>5 for all Gynecare TVT, all products, and there were three</p> <p>6 MDRs filed with the FDA. Only one of them was for</p> <p>7 Secur, and it was filed not by the company but by a user</p> <p>8 facility, and I printed it out, and it was for a bent</p> <p>9 device. It wasn't for a patient injury, it was a bent</p> <p>10 device that the doctor had, and they had to send it</p> <p>11 back. So there were three, a total of three MDRs.</p> <p>12 Then I looked at the year 2008 and 2009.</p> <p>13 There were nine MDRs for all of TVT. Two of those were</p> <p>14 for Secur. So 2008, 2009.</p> <p>15 Now, internally we're seeing discussions of</p> <p>16 Germany and Australia, failures for people like Lucente,</p> <p>17 and they're not being captured in the MDRs. They should</p> <p>18 be, because the IFU and the labeling doesn't have the</p> <p>19 severity and the frequency with which reports of</p> <p>20 erosion, dyspareunia is occurring and failure. So that</p> <p>21 information would be required to be reported to the FDA,</p> <p>22 in terms of the regulations, 21 C.F.R. 803.</p> <p>23 Year 2009 through 2010, there's eight reports,</p> <p>24 and there is one Secur report in those eight, and it was</p>	<p style="text-align: right;">Page 73</p> <p>1 those 500 I counted were Secur, which is a small</p> <p>2 percentage, really, of over 500 reports. I could go</p> <p>3 month by month and find out what the total would be, but</p> <p>4 I think it makes its point, that FDA was really not</p> <p>5 getting Medical Device Reports from the company until</p> <p>6 2013, and yet their records show that they were aware of</p> <p>7 issues before that, and they're not getting a lot of</p> <p>8 reports for Secur.</p> <p>9 I mean, in 2013, they have 61 reports out of</p> <p>10 500. That's a small percentage that's Secur. The year</p> <p>11 2014 to 2015, there's 500 records.</p> <p>12 So if you're going to say that they're</p> <p>13 required to report Medical Device Reports to the FDA to</p> <p>14 notify the FDA or alert the FDA of a safety signal or an</p> <p>15 issue with their product, there's no signal here for</p> <p>16 Secur until -- or anything with TVT until 2014, 2013.</p> <p>17 So they're not filing MDR reports as they're</p> <p>18 required to do, and if a physician knew how to look up</p> <p>19 MDR reports, say, any physician who decided, I'm going</p> <p>20 to use this device versus another, the MDRs really are</p> <p>21 fairly silent. There's not a lot of reports. So</p> <p>22 I think that feeds into that opinion.</p> <p>23 Q All right. Dr. Parisian, have we discussed</p> <p>24 all of your post-marketing --</p>



1 A No, no, that's just getting started.

2 MR. HUTCHINSON: All right. Well, I'll tell  
3 you what. I'm going to -- and we'll -- I told everybody  
4 that at the beginning of this deposition that I'm trying  
5 to be respectful for the witness' time, but we're just  
6 simply not going to finish today if we continue down  
7 this path.

8 So I'm going to ask, Dr. Parisian, if you  
9 would, just in an effort for me to be respectful for  
10 your time and your -- Mr. Lundquist's time, if you could  
11 stick with my question, so we can kind of move on.

12 MR. LUNDQUIST: And hold on, Doctor.

13 I mean, with all due respect, Chad, you're  
14 asking a pretty broad question, on the -- you're asking  
15 her the basis for her opinion. She's given it to you.

16 MR. HUTCHINSON: Okay.

17 MR. LUNDQUIST: I think she's being actually  
18 fairly as succinct as she can, over a six-year period,  
19 with some of these MDR reports. And to be clear,  
20 I mean, we will be finished today after six hours on the  
21 record. If you want more time, obviously, you have to  
22 take that up with the judge.

23 MR. HUTCHINSON: Okay.

24 MR. LUNDQUIST: But if you want to ask her

1 my tab 45, this is a presentation May 15th, 2007 at the  
2 European Feedback Board Update, and the company's  
3 talking about the failure rates in terms of the TVT  
4 Secur. They knew that the TVT-O had had a failure rate  
5 from early experience of 89 percent, whereas the TVT  
6 Secur was 74 percent. They knew the Monarc was  
7 supposedly 91 percent.

8 They talk about the things they knew about the  
9 device and the problems with it. The issue of tension  
10 was discussed in that meeting. They said that there's  
11 large variations of the surgical procedures. They said  
12 results on incontinence are not consistent with  
13 70 percent rather than 90 percent, results were  
14 unpredictable. So that would be another example, with  
15 the European experiences.

16 They were saying that in 2007, that the key  
17 experts and nonexperts are disappointed with the product  
18 and are abandoning the procedure. They said that there  
19 was no advantage over the conventional TVT and to accept  
20 these failures that they're seeing. They're already  
21 talking about coming up with another device, Dr. Leval's  
22 mini TVT-O. So that's 2007.

23 The Australian would be around.... So  
24 internally, they were getting information that the

1 more specific questions, perhaps --

2 BY MR. HUTCHINSON:

3 Q Doctor --

4 MR. LUNDQUIST: You understand where I'm  
5 coming from, as well.

6 BY MR. HUTCHINSON:

7 Q Dr. Parisian, your opinions on post-marketing  
8 surveillance relates no clinical data, the filing or not  
9 filing of the MDR reports. Any other opinions?

10 A Yes. In 2007, the German complaints they  
11 received, January 2007, my tab 49, they received  
12 complaints from Germany of 49 reports of failures, at  
13 four to 12 weeks.

14 They also had complaints of Australia, the  
15 Australian issue in 2007, that they were having problems  
16 in Australia with the three key opinion leaders in  
17 Australia having a 65 percent failure rate, a 30 percent  
18 failure rate and a 45 percent failure rate. Those were  
19 post-market, because this is the performance of the  
20 device in human beings outside the United States.

21 Q Anything else?

22 A So, yeah, Germany, let's see... I would say  
23 also the European experience that the company had in  
24 2007, talking about that the -- and this would be under

1 product was having problems.

2 Q Anything else, on post-marketing?

3 A Okay, let's see. Well, again, this would be a  
4 document that was -- we're talking about what  
5 happened -- what did they have before June 2010 on  
6 Ms. Garcia's surgery.

7 Q No, I'm asking you about any other opinions  
8 about post-marketing.

9 A No, but I tried to testify on that  
10 particularly. So there is a presentation, Incontinence  
11 Platform, August 19th, by Harel Gadot, which would be  
12 also in Europe, and he's talking about the International  
13 UGA abstract, that there was de novo urgency reported in  
14 the abstracts, and 4.2 percent voiding dysfunction.

15 So there was information from Europe  
16 Dr. Lucente experienced at six weeks. He had -- he was  
17 having a high failure rate, and that's Dr. Lucente,  
18 who's one of the key people for this product. They know  
19 that there's a huge -- that the learning curve is great.  
20 So this is all post- -- this is all post-market issue.

21 And this is where they say in the  
22 presentation, "It is completely different than the TVT  
23 and the TVT-O." That's significant, because the 510(k)  
24 cleared it to be marketed only because it was

<p style="text-align: right;">Page 78</p> <p>1 substantially equivalent. So internally, the company's</p> <p>2 aware from the European data that it's not a substantial</p> <p>3 equivalent. That would then make it by definition an</p> <p>4 adulterated device. It wasn't the device cleared by the</p> <p>5 FDA.</p> <p>6 Q Anything -- any other opinions regarding</p> <p>7 post-marketing surveillance?</p> <p>8 A Okay. User error is a post-market issue, and</p> <p>9 they have --</p> <p>10 Q Okay, tell me about your opinions about user</p> <p>11 error, please.</p> <p>12 A Tab 41 begins with the Germany experience,</p> <p>13 poor experience in tensioning, and then tab 42,</p> <p>14 March 2007, there is discussion about the learning</p> <p>15 curve, longer learning curve; mesh tensioning was</p> <p>16 different than any of the other kits. Tab 42.</p> <p>17 Tab 43, which is a March 2007 e-mail, early</p> <p>18 results of TVT Secur, they're saying that the tension</p> <p>19 isn't tight enough. So tension, 30 percent recurrence,</p> <p>20 that I know about, in terms of that tab, early results</p> <p>21 of TVT Secur. And the salespeople are -- in Europe are</p> <p>22 asking about the rumor that there's 30 percent</p> <p>23 incontinence.</p> <p>24 Q And -- sorry.</p>	<p style="text-align: right;">Page 80</p> <p>1 train people.</p> <p>2 Well, you don't do that. If there's a user</p> <p>3 error or problem, you don't just allow them to continue</p> <p>4 to use it to keep the product on the market.</p> <p>5 Q Anything else?</p> <p>6 A They didn't conduct a recall in the United</p> <p>7 States. When they knew that the product was not</p> <p>8 performing as it was cleared, and it was adulterated and</p> <p>9 it wasn't safe and effective, they didn't stop sales,</p> <p>10 they didn't contact physicians, like Dr. Miklos,</p> <p>11 Dr. Walss, and let them know about the potential risks</p> <p>12 with this product, particularly for the women who were</p> <p>13 implanted already, and they continued to market a</p> <p>14 product that was defective, basically, in terms of 21</p> <p>15 C.F.R. 806. It should have actually been -- marketing</p> <p>16 should have been stopped. There are plenty of other</p> <p>17 products.</p> <p>18 Q Anything else?</p> <p>19 A That you continue to market an adulterated</p> <p>20 device?</p> <p>21 Q Yes, ma'am. Anything else, any other opinions</p> <p>22 related to post-marketing?</p> <p>23 A Well, in all that post-marketing, they also</p> <p>24 knew the pre-marketing flaws, in terms of what I had</p>
<p style="text-align: right;">Page 79</p> <p>1 A So those are post-market.</p> <p>2 Q Any other opinions about post-market,</p> <p>3 Dr. Parisian?</p> <p>4 A Well, I would definitely send you to tab 44,</p> <p>5 which is a PowerPoint presentation called "TVT Secur"</p> <p>6 before the Quality Board.</p> <p>7 Q Yeah, I'm not -- I'm not going to get to the</p> <p>8 documents that you looked at. I just want to know what</p> <p>9 your opinions were on what Ethicon did wrong in</p> <p>10 post-marketing.</p> <p>11 A Okay, well, they weren't filing MDRs. They</p> <p>12 weren't doing a corrective and preventive action to</p> <p>13 correct the issues that are being described when they</p> <p>14 know their product's not substantial equivalent. Can't</p> <p>15 do that under 21 C.F.R. 820. So you can't market a</p> <p>16 product that you have all these signals from post-market</p> <p>17 that it's not performing like you're cleared.</p> <p>18 Q Anything else?</p> <p>19 A Well, in terms of post-marketing, in terms of</p> <p>20 Australia, where they're having problems, the company</p> <p>21 says, in this Quality Assurance -- Quality Board</p> <p>22 presentation, that despite knowing that the product is</p> <p>23 failing in Australia and there's an issue, that they're</p> <p>24 going to keep the product in the market in order to</p>	<p style="text-align: right;">Page 81</p> <p>1 originally said about their design, testing, sheep.</p> <p>2 So that should have all been something that</p> <p>3 should have raised a red flag, because they knew the</p> <p>4 background of this product, and the other products. So</p> <p>5 they should have incorporated a comparison of the</p> <p>6 products already being sold into their post-market.</p> <p>7 So you didn't have notification of physicians.</p> <p>8 You didn't have notification of the FDA, because you</p> <p>9 didn't have MDRs being filed. You didn't have FDA being</p> <p>10 told the product isn't performing the way it was</p> <p>11 supposed to. You had continuing marketing of a product</p> <p>12 that was not -- that was not performing the way it was</p> <p>13 supposed to. You didn't have updating of the IFU to</p> <p>14 inform people of the risk of the frequency.</p> <p>15 Q Okay.</p> <p>16 A You didn't have updating of the IFU in terms</p> <p>17 of CAPA, as to which patient should this be used for,</p> <p>18 because they make a claim to the FDA that it's only</p> <p>19 certain patients, and in Australia they're proposing,</p> <p>20 well, maybe we'll tell the Australians it's obese women</p> <p>21 or really healthy women. So they don't narrow down who</p> <p>22 is this device for --</p> <p>23 Q Okay.</p> <p>24 A -- and is there any benefit of this device.</p>



1 And so I think notification, continued marketing, no  
2 reporting, failure to correct the problem --

3 Q Anything else?

4 A That's quite a bit. Let me think about that.

5 Q All right. Have we discussed all of your  
6 opinions as they relate to the pre-marketing and  
7 post-marketing of TVT Secur?

8 A Let me look at this a minute. Well, I think  
9 my other opinion is that this product wasn't going to  
10 work. I mean, they didn't convey to physicians this  
11 unpredictability, and I think Dr. Miklos will actually  
12 testify about that more, but it was, like, Dr. Walss and  
13 all other physicians using this product were doomed  
14 because, for one, they say there's a learning curve;  
15 some people say there's over a hundred patients; they  
16 don't have good instructions in terms of tensioning.

17 There's no way that you could use this  
18 product -- the KOL, the key guys, in 2006, were having a  
19 hard time using it. So if the key users can't use it  
20 reliably, then who -- what other physicians are going to  
21 use this product?

22 So it's failing of the company to tell the  
23 doctors that this is a really risky product and there's  
24 a high risk, and do you really want to use it? And

1 that needs to be included too, because the patient  
2 brochure was -- the one I have is generated in 2008, and  
3 it says, if -- the only number in there is 97 percent.  
4 So for TVT family, it says that you're going to have  
5 a -- it implies a 97 percent success rate.

6 So if a woman received such a brochure, it  
7 doesn't have adequate information about risks or  
8 warnings, in terms of the differences in the risk for a  
9 TVT-O versus TVT, versus a TVT Secur. That information  
10 is not in there. They just put them all together as a  
11 TVT family, and I think that's misleading in terms of 21  
12 C.F.R. 801.109, that's adequate prescription labeling,  
13 and FDA uses that also to apply to a direct-to-consumer  
14 information.

15 BY MR. HUTCHINSON:

16 Q And that's --

17 A So you have to be truthful and accurate there.

18 Q I'm sorry. Are you finished?

19 A I think so.

20 Q Okay. Have we now discussed all of your  
21 opinions as they relate to the pre-marketing and  
22 post-marketing of TVT Secur and the bases for those  
23 opinions?

24 A Well, we haven't talked about bases. You

1 I think that my tabs for that would be tab 48, tab 47,  
2 tab 49, tab 53, 54, and 58, and then also Dr. Miklos,  
3 because he had been a preceptor, and he said how  
4 difficult it is to place.

5 So it's like -- it's like getting a product  
6 with -- from Home Depot with Chinese instructions, and  
7 no one's ever going to put it together, and that's  
8 basically what's happening, and so it's getting blamed  
9 on user error, but there's a point where it's not user  
10 error, it's design error that's also contributing to the  
11 user error, and so that goes back to design flaws of the  
12 pre-market.

13 Q Have we discussed now all of your  
14 pre-marketing and post-marketing opinions and the bases  
15 for those opinions?

16 A Well, the other one would include that  
17 post-market, they're not informing the FDA. So that's  
18 actually kind of its own opinion.

19 Q Have we now discussed all of your opinions, as  
20 they relate to the TVT Secur?

21 MR. LUNDQUIST: Post-market or pre-market?  
22 Yeah, okay.

23 THE WITNESS: We didn't touch on the user  
24 brochure. In my book, there's a patient brochure, and

1 haven't wanted me to go through the bases, but these are  
2 my opinions as to them. We've talked about what my  
3 opinions are, and then I've been trying to lead you to  
4 the bases, but we haven't discussed those.

5 Q Okay, well, I need to find out all the bases  
6 for your opinions, too.

7 A I know. I've been trying to provide it to  
8 you.

9 Q Well, if you could -- if you could do that for  
10 me, I'd appreciate it.

11 A Well, that's why I'm trying to give you the  
12 bases in terms of the tabs --

13 Q Okay.

14 A -- so you know which documents I'm looking at,  
15 and we can go through those documents specifically, but  
16 I was trying to shorten it, to give you the opinions.

17 Q Okay.

18 A That's what you asked. That's what  
19 I understood you to ask.

20 Q Okay. Have we now discussed all of your  
21 opinions as they relate to the pre-marketing and  
22 post-marketing of TVT Secur?

23 A Well, I also read Dr. Walss' testimony and  
24 I think my opinions are relevant in terms of his use of

1 the choice of this product to implant in Ms. Garcia, to  
2 bring this back to Ms. Garcia; and also Dr. Miklos.  
3 I think they're consistent with what Dr. Miklos says in  
4 terms of his understanding.

5 So the post-market are further supported in  
6 Ms. Garcia's case by both of those physicians, in terms  
7 of their experience with these products from a clinical  
8 standpoint.

9 Q Okay. Have we now discussed all of your  
10 opinions as they relate to the pre-marketing and  
11 post-marketing of TVT Secur?

12 A As topics. We can go through specific  
13 documents and I can show you the basis for each one of  
14 those opinions.

15 Q But as topics, we've covered them all,  
16 correct?

17 A I've been trying to summarize it all into --  
18 let's see. In terms of the post-market, I think the  
19 Australian is important, and it's another opinion, in  
20 that the FDA wasn't told about the potential risks for  
21 Australia. The company never conducted a recall in  
22 Australia. They had a Dear Doctor letter, so that they  
23 were going to update training. Physicians didn't want  
24 retraining, and the company was thinking about

1 introducing this product to block off the Miniarc.

2 And that information, FDA's required to have  
3 that information, too, in terms of post-market safety  
4 information about a product that's being marketed. That  
5 would be significant to FDA, that the Austr- -- human  
6 data, no matter where the source, is significant to the  
7 FDA in terms of safety, patient safety, because when  
8 products are cleared, there's little human data.

9 And so the Germany experience and the  
10 Australian experience should have been told to the FDA  
11 in some fashion.

12 Q Okay.

13 A And it wasn't, and so that also would be  
14 misbranding of your device in terms of 21 U.S.C. 352(t),  
15 small T, that you have to provide reports to the FDA,  
16 and that would be information that needs to be safety  
17 information, even for a 510(k), that needed to be  
18 communicated to the FDA, whether it was MDRs or it was  
19 just direct notification of the FDA.

20 Q Have we now discussed all of your opinions?

21 A And also, more importantly, as Dr. Walss said,  
22 that would have been important to him to have known  
23 about, and also Dr. Miklos; so not only to communicate  
24 it to the FDA, but to communicate it to the physicians.

1 Q Have we now discussed all of your opinions --  
2 MR. LUNDQUIST: Form.

3 BY MR. HUTCHINSON:

4 Q -- as to the post-marketing and pre-marketing  
5 of TVT Secur?

6 A There's a lot of opinions there.

7 Q I'm not asking you how many, I'm just asking  
8 if we've discussed them all.

9 A Let's see. I'm trying to... Well, in  
10 post-market, I think there's also, I believe, in tab 44,  
11 when they're talking about the challenges, lessons  
12 learned, the company as part of their post-market --

13 Q I want to talk about your opinions, not what  
14 the document says.

15 A No, the opinions --

16 Q Tell me what your opinion is.

17 A The opinion is that the company identified  
18 that the rush to market without clinical data was a  
19 significant factor in terms of the failure of this  
20 product in terms of, to succeed. So that would mean  
21 that the company identified that as a post-market issue,  
22 that they weren't going to do that in the future is what  
23 they said, and that would come out of tab 44, and they  
24 said that in 2007, years before Ms. Garcia was

1 implanted.

2 In tab 50, the company was aware that it was  
3 suboptimal performance.

4 Q Do you have any other -- I'm sorry.

5 A Yeah, and then the marketing, we haven't  
6 talked about the marketing, because marketing actually  
7 would fit under post-market issues too, in terms of the  
8 information that the physicians were being told about  
9 the success and performance of this product, that was  
10 not acceptable too. The claims that were being made for  
11 this product as being less invasive, less risky, it's  
12 implying it's a safer device and it's not, in terms  
13 TVT-O and TVT. So marketing is another issue.

14 So we have physician notification, FDA  
15 notification, we have a learning curve, training,  
16 tensioning, we have marketing claims, we have failure to  
17 communicate risks even to patients, doctors, and failure  
18 to file MDRs, failure to make effective CAPAs, in terms  
19 of quality assurance, continuing to market an  
20 adulterated device, prohibited act, 21 U.S.C. 331(a) and  
21 (b).

22 Also, and we haven't talked specifically about  
23 the IFUs. We'll talk about that.

24 Q We'll get to the IFUs in a minute, but is that

<p style="text-align: right;">Page 90</p> <p>1 a fair summary, what you just gave, of all your opinions</p> <p>2 as related to the pre-marketing and post-marketing of</p> <p>3 the TVT Secur?</p> <p>4 A Yeah, and then what they had learned --</p> <p>5 Q And I'm sorry, is that a yes?</p> <p>6 A I think so, and what they had learned in terms</p> <p>7 of the next generation, which was, by 2008, they're</p> <p>8 already talking about what they were going to do with</p> <p>9 the next device.</p> <p>10 So there is this post-market where they're</p> <p>11 moving on to another device already before Ms. Garcia is</p> <p>12 implanted, and then -- let's see.</p> <p>13 Also the communication with the FDA in terms</p> <p>14 of the 522, not doing the 522. The communication is not</p> <p>15 that this is -- we're taking this off the market because</p> <p>16 it's a dangerous device. The company told the FDA,</p> <p>17 supposedly, based on the company's documents, that it</p> <p>18 was a safe device and we were just making a marketing</p> <p>19 decision, and it's not accurate. That would fit into</p> <p>20 the FDA reporting.</p> <p>21 Q Okay.</p> <p>22 A But they didn't get a 522, and then they</p> <p>23 closed the registry, in terms of post-market</p> <p>24 information. They had opened a registry, they knew they</p>	<p style="text-align: right;">Page 92</p> <p>1 THE WITNESS: That would be fine. I'd like</p> <p>2 that.</p> <p>3 (Deposition in recess from 10:55 a.m. to 11:04 a.m.)</p> <p>4 BY MR. HUTCHINSON:</p> <p>5 Q Dr. Parisian, we're back on the record. You</p> <p>6 realize that?</p> <p>7 A Yes.</p> <p>8 Q Are you ready to go?</p> <p>9 A Yes, sir.</p> <p>10 Q Okay. Now, you're a pathologist, is that</p> <p>11 correct?</p> <p>12 A Yes, sir.</p> <p>13 Q Last time you treated a living patient was</p> <p>14 when?</p> <p>15 A In the 1980s. I was a company doc.</p> <p>16 Q You're not a member of the American Medical</p> <p>17 Association?</p> <p>18 A No, no, I am.</p> <p>19 Q You are?</p> <p>20 A Yes.</p> <p>21 Q How long have you been a member of the</p> <p>22 American Medical Association?</p> <p>23 A For years.</p> <p>24 Q More than 10 years?</p>
<p style="text-align: right;">Page 91</p> <p>1 needed clinical data, and they closed it prematurely,</p> <p>2 without the data, and we don't have the follow-up to</p> <p>3 what happened to that registry data. So that's another</p> <p>4 post-market issue.</p> <p>5 Q So have we now discussed all your opinions as</p> <p>6 it relates to the pre-marketing and post-marketing of</p> <p>7 the TVT Secur?</p> <p>8 A I think also, I would reference Dr. Miklos'</p> <p>9 report --</p> <p>10 Q Well, instead of referencing reports, I want</p> <p>11 to talk about your opinions.</p> <p>12 A Yeah.</p> <p>13 Q Okay.</p> <p>14 A But --</p> <p>15 Q So why don't you tell me: Have we discussed</p> <p>16 all of your opinions as they relate to the pre-marketing</p> <p>17 and post-marketing of TVT Secur?</p> <p>18 A We have discussed my opinions other than the</p> <p>19 IFU. I said we haven't specifically discussed the IFU.</p> <p>20 Q All right, thanks.</p> <p>21 Your lawyer -- I mean, I'm sorry --</p> <p>22 Ms. Garcia's lawyer has asked to take a quick bathroom</p> <p>23 break. So why don't we go off the record for just a</p> <p>24 second.</p>	<p style="text-align: right;">Page 93</p> <p>1 A More than 10 years, yeah.</p> <p>2 Q Okay. Have you ever been board-certified in</p> <p>3 internal medicine?</p> <p>4 A No, sir, just pathology, anatomic and</p> <p>5 clinical.</p> <p>6 Q Do you have any staff privileges at any</p> <p>7 hospital?</p> <p>8 A No, sir.</p> <p>9 Q Are you credentialed at any hospital?</p> <p>10 A No, not right now. I'm licensed, but not</p> <p>11 credentialed.</p> <p>12 Q You're not a biostatistician?</p> <p>13 A That's not my training. I've used biostats</p> <p>14 for different issues, but I'm not -- that would not be</p> <p>15 what I would put myself out as.</p> <p>16 Q Or an epidemiologist?</p> <p>17 A Only in that I've done epidemiology for the</p> <p>18 FDA. I have hands-on epidemiology, but I don't have a</p> <p>19 degree in epidemiology.</p> <p>20 Q But you're not holding yourself out as an</p> <p>21 expert in epidemiology, correct?</p> <p>22 A Not for this litigation.</p> <p>23 Q Or a toxicologist?</p> <p>24 A I've been trained -- I can run a toxicology</p>

1 lab as a pathologist, but I'm not discussing toxicology  
2 for this litigation. I've had no toxicology in terms of  
3 FDA.

4 Q You're not -- I'm sorry.

5 A Well, because I had to look at animal data.  
6 They didn't -- as a pathologist, they used me also to do  
7 a lot of toxicology work for devices.

8 Q You're not a polymer scientist, biomaterial  
9 engineer or behavioral scientist, correct?

10 A Those aren't my specialties. I've been  
11 involved in all those issues.

12 Q You're not a surgeon?

13 A That is correct.

14 Q Not a gynecologist?

15 A Well, I did a lot of gynecology in terms of  
16 general practice. So I've done it as a family  
17 practice-type situation, but I'm not a gynecologist.

18 Q What about a urologist?

19 A No, I'm not a board-certified urologist. I've  
20 done some urology. I mean, I'm assuming you're talking  
21 about someone that's your specialty every day. Yes,  
22 I am not a practicing urologist.

23 Q And you're not a urogynecologist, either, are  
24 you?

1 A I'm not a practicing urogynecologist, but I'm  
2 a pathologist. So in terms of the anatomy, I'm aware of  
3 the anatomy and the issues about it.

4 Q You're not an expert in SUI?

5 A Only in the regulatory issues for SUI. I'm  
6 not a person who would treat patients for SUI.

7 Q Not in the medical sense, correct?

8 A Yes, correct.

9 Q And in fact, you're not an expert in any of  
10 the medical specialties that may be at issue in this  
11 case, correct?

12 MR. LUNDQUIST: Object, form.

13 THE WITNESS: I'm an FDA regulatory expert. A  
14 pathologist does have some role. I'm not your  
15 pathologist, there's a pathologist, but I have that  
16 clinical training and background as an FDA medical  
17 person.

18 So I don't know what you're -- I mean, I'm  
19 not -- I'm an FDA medical officer. So I'm talking about  
20 regulatory issues for a medical device in a particular  
21 case, so --

22 BY MR. HUTCHINSON:

23 Q Well, I'm asking you if you're an expert in  
24 any of the medical specialties that are at issue in this

1 case. Medical specialties, not FDA regulatory, medical  
2 specialties.

3 MR. LUNDQUIST: Form.

4 THE WITNESS: The medical specialties would be  
5 anatomic clinical pathology, but I'm not -- that is not  
6 my sole role here.

7 BY MR. HUTCHINSON:

8 Q And you're not an expert in determining  
9 corporate motive or intent, are you?

10 A I wouldn't even do that. The only thing  
11 I would use is documents that state what the intent or  
12 motive is, not a subjective intent or motive, that's  
13 correct, but what the documents in evidence support, or  
14 what their testimony is. That would be them saying what  
15 their intent was.

16 Q Do you know what the current gold standard for  
17 the treatment of SUI is?

18 A No, not -- I don't know right now what today  
19 it is, because there's a lot of options, and also the  
20 SUI can have -- the degree with which the woman has SUI  
21 would determine the options, whether she goes through in  
22 surgery or whether she goes to minimally invasive or  
23 whether she doesn't get anything now and uses Kugel  
24 exercises, just those with pads. So I don't know what

1 the gold standard is.

2 Q Are you familiar with the American  
3 Urogynecological Society or the American Urology  
4 Associates or Association, or the International  
5 Urogynecological Association?

6 A I'm familiar with the words and what they've  
7 done and their involvement in some of the SUI issues.

8 Q Are they well respected societies within the  
9 field?

10 A They are the societies for the field. Well  
11 respected by who? I mean, there are people join them.  
12 Some of those fields actually had begun some of the  
13 concerns about SUI and mesh products.

14 Q Would you consider them leaders in the field,  
15 these societies?

16 A They are societies for those fields, so  
17 there's nobody -- so they would be the leaders for those  
18 fields, because they're professional organizations.

19 Q Would you consider them well respected?

20 A Yeah, doc --

21 Q Within the medical community?

22 A Yeah, I have no reason to -- I mean, it's like  
23 the AMA. Is the AMA well respected in the medical  
24 community? It's a professional organization. People

<p style="text-align: right;">Page 98</p> <p>1 join it.</p> <p>2 Q And you relied, in reaching some of your</p> <p>3 opinions, in part, on some of the literature from these</p> <p>4 societies, correct?</p> <p>5 A Yeah, and some of their meetings and some of</p> <p>6 their concerns, when they were concerned, I think around</p> <p>7 at 2006, about the safety of surgical mesh. They</p> <p>8 actually were bringing it to the forefront. FDA</p> <p>9 actually was responding to the specialists who were</p> <p>10 concerned about SUI and pelvic floor replacement, POP</p> <p>11 procedures.</p> <p>12 Q Have you ever diagnosed, treated or managed</p> <p>13 SUI?</p> <p>14 A Yeah, sure. I mean, I've had women with SUI,</p> <p>15 and you tell them what it is, and you talk to them about</p> <p>16 what the options would be, and just -- that was back in</p> <p>17 the 80's.</p> <p>18 Q And you did that when you were a pathologist?</p> <p>19 A No, when I was treating real people, living</p> <p>20 patients, back in the 80's. I was the company doctor at</p> <p>21 Avtex, and I was the first -- you would have patients</p> <p>22 come in and they would explain what their problems were,</p> <p>23 and then I would have to send them to somebody else,</p> <p>24 refer them. So yeah, I would have to talk to them about</p>	<p style="text-align: right;">Page 100</p> <p>1 in any person's body, correct?</p> <p>2 A Um, I don't know if I have. I mean, I put</p> <p>3 sutures in people. I mean, I've done lacerations.</p> <p>4 I don't know if I've never -- I've assisted when they've</p> <p>5 implanted devices. I've not been the primary implanter</p> <p>6 of, like, a hip implant or something like that.</p> <p>7 Q And do you have any expertise in implanting</p> <p>8 medical devices in any way?</p> <p>9 A I don't know, because you're talking about a</p> <p>10 history going back to the 70's, and so I don't know.</p> <p>11 Q Okay.</p> <p>12 A Um, medical devices -- I mean, I wouldn't say</p> <p>13 I'm a cardiologist, I didn't do pacemakers, so I didn't</p> <p>14 do any specialized devices, but to say I've never</p> <p>15 implanted a medical device, I don't know.</p> <p>16 Q Do you -- well, that's not my question. My</p> <p>17 question was, do you have any expertise in implanting</p> <p>18 medical devices?</p> <p>19 A From the regulatory point of view --</p> <p>20 Q I'm not asking for the regulatory, if</p> <p>21 you don't mind, I'm asking for a medical standpoint. Do</p> <p>22 you hold yourself out as having expertise in implanting</p> <p>23 medical devices?</p> <p>24 A I've been around where medical devices -- I've</p>
<p style="text-align: right;">Page 99</p> <p>1 SUI.</p> <p>2 Q Right, but you never managed a patient with</p> <p>3 SUI or treated a patient with SUI, did you?</p> <p>4 A I would have referred them to somebody or told</p> <p>5 them what their options were. Oftentimes they chose not</p> <p>6 to do anything.</p> <p>7 Q Have you ever participated in a cadaver study</p> <p>8 or an animal study about mesh?</p> <p>9 A Not about mesh. I've participated in a lot of</p> <p>10 cadavers, but not about mesh.</p> <p>11 Q Anything about any foreign SUI product?</p> <p>12 A Pardon?</p> <p>13 Q Have you ever participated in a cadaver or</p> <p>14 animal manual study for any type of product?</p> <p>15 A I didn't participate. I've consulted for</p> <p>16 manufacturers who was working with the product they</p> <p>17 wanted to get cleared.</p> <p>18 Q Have you ever seen how a TVT Secur product is</p> <p>19 implanted in the body?</p> <p>20 A Physically seen it, no.</p> <p>21 Q I take it you've ever implanted a TVT Secur</p> <p>22 device in somebody's body.</p> <p>23 A You are right, I never have.</p> <p>24 Q And nor have you implanted any medical device</p>	<p style="text-align: right;">Page 101</p> <p>1 been in the OR when medical devices are implanted and</p> <p>2 I've also removed medical devices after they've been</p> <p>3 implanted. So I do have some hands-on expertise about</p> <p>4 the biocompatibility and the effect in the body of</p> <p>5 medical devices. I don't have a specialty that had a</p> <p>6 specific device that they're implanting for a procedure,</p> <p>7 but the working parts of the body for implantation,</p> <p>8 yeah, I'm familiar with that.</p> <p>9 Q Have you ever designed any clinical trials</p> <p>10 regarding mesh?</p> <p>11 A Not for mesh.</p> <p>12 Q Any type of SUI product?</p> <p>13 A I did not design it. I reviewed it. So that</p> <p>14 was the radiofrequency trials.</p> <p>15 Q You've never been involved in any clinical</p> <p>16 research regarding mesh, have you?</p> <p>17 A No.</p> <p>18 Q Or SUI?</p> <p>19 A No.</p> <p>20 Q You've never designed pelvic mesh?</p> <p>21 A No.</p> <p>22 Q Or any type of SUI product?</p> <p>23 A Only consulted on someone who was working with</p> <p>24 one.</p>

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1 Q And I think we talked about this earlier, but  
 2 you've never done any type of biomechanical testing for  
 3 pelvic mesh or any SUI product, correct?  
 4 A Correct. FDA wouldn't do that.  
 5 Q In fact, you've never inspected a mesh  
 6 explant, have you?  
 7 A Yeah, I've done that. I mean, I've seen  
 8 explanted mesh.  
 9 Q Have you ever inspected -- I'm not asking if  
 10 you've seen one, I'm asking if you've inspected one.  
 11 A Well, I've -- surgical path, you remove  
 12 explanted mesh. I don't know what you -- I meant looked  
 13 at it and examined measured it and the qualities of it.  
 14 I don't know what you mean by "inspect."  
 15 Q Did you ever inspect -- well, did you ever  
 16 inspect a piece of mesh for any types of degradation?  
 17 Have you ever done that before?  
 18 A Not in the laboratory setting specifically.  
 19 I would be looking at it grossly.  
 20 Q You've never performed a DDSA, have you?  
 21 A No.  
 22 Q You've never performed an FMEA, have you?  
 23 A Wait a second, wait. Go back. The DD -- what  
 24 did you say?

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1 Q DDSA.  
 2 A Yeah, what are you saying is a --  
 3 Q Do you know what DDSA stands for?  
 4 A I don't know what it --  
 5 Q What about a Design Device Safety Analysis,  
 6 have you ever --  
 7 A Oh, that, yes --  
 8 Q -- performed a Design --  
 9 A -- but I haven't used that term for it.  
 10 THE REPORTER: Wait, one --  
 11 MR. HUTCHINSON: Wait a minute, one person at  
 12 a time.  
 13 THE REPORTER: Yeah, one person at a time.  
 14 BY MR. HUTCHINSON:  
 15 Q Have you ever performed a design -- I'm sorry,  
 16 scratch that. Have you ever performed a Device Design  
 17 Safety Analysis for a mesh product?  
 18 A Not for a mesh product.  
 19 Q Or any type of SUI product?  
 20 A I've reviewed the ones that the companies  
 21 have.  
 22 Q Have you ever performed a Failure Mode  
 23 Evaluation Analysis for any type of mesh product?  
 24 A No, reviewed them.

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1 Q Have you ever done an FMEA for any type of SUI  
 2 product?  
 3 A I've only reviewed them, because they're the  
 4 company documents that I learned to review at the FDA.  
 5 Q You're not an expert on how mesh performs in  
 6 the body, are you?  
 7 A Yes, I am, in terms of what -- in terms it  
 8 being a FDA reviewer, medical officer, you have to look  
 9 at the effects of mesh, and one of the things would be  
 10 shrinkage, contraction, infection, the porosity in terms  
 11 of the migration of certain cells through the pores. So  
 12 yes, I've looked at issues for that for mesh for the  
 13 FDA --  
 14 Q You're not --  
 15 A -- and degradation, and then your double-sided  
 16 meshes which would have a side that -- yes, so I've had  
 17 to do that for FDA.  
 18 Q You're not an expert in the design process for  
 19 pelvic mesh, are you?  
 20 A Not in the design process. I had to review,  
 21 but not design.  
 22 Q Or any type of product -- SUI product.  
 23 A The design process -- I mean, I've had to look  
 24 at all the -- I had to look at clinical studies for the

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1 manufacturer. I don't know about -- I mean, I've looked  
 2 at clinical studies for radiofrequency trying to show  
 3 them to be safe and effective, get clearance from the  
 4 FDA. So I don't know what --  
 5 Q But you're not an expert in the design process  
 6 of any SUI product.  
 7 A The original design, that's correct.  
 8 Q Okay. You've never invented a medical  
 9 product, have you?  
 10 A Well, I helped develop a medical product.  
 11 I don't have a patent, in terms of a product that was to  
 12 be implanted.  
 13 Q Do you have any expertise in designing or  
 14 developing a medical product?  
 15 A Sure.  
 16 Q Other than from a regulatory standpoint?  
 17 A Well, no, no, as a consultant and working with  
 18 a manufacturer to bring a new product to the market,  
 19 I have to -- you participate with people who were  
 20 creating the device, the how do you select materials,  
 21 what standards do you use, what kind of information  
 22 would you tell the FDA. So yeah, I've done that.  
 23 Q Well, let's talk about when you were at the  
 24 FDA. You were there from '91 to '95, is that right?



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1 A Yes, sir.  
 2 Q What, 20 years ago?  
 3 A Yes, sir.  
 4 Q Did you have a computer when you worked with  
 5 FDA?  
 6 A Yes, sir, we did. I learned how to use  
 7 WordPerfect; the FDA taught me how. It was a really  
 8 crappy computer.  
 9 Q What kind of computer did you have?  
 10 A It was -- I don't remember what kind it was,  
 11 but it was -- it was not good. But yeah, they sent me  
 12 to computer classes to use it on, but you didn't have  
 13 access to the internet. At that point in time, FDA  
 14 reviewers weren't allowed to use the internet.  
 15 Q Did you or anyone that you worked with at the  
 16 FDA have a laptop?  
 17 A Sure. There were laptops, but you had to buy  
 18 your own laptop.  
 19 Q Did you or anyone you worked with at the FDA  
 20 have a cell phone?  
 21 A No, there weren't cell phones back then.  
 22 I don't think there were cell phones. No, I don't  
 23 remember cell phones.  
 24 Q You're not here as a representative of FDA,

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1 FDA, as today?  
 2 A No, it was disbanded by Dr. Kessler and  
 3 Dr. Burlington in 1993, and the few medical officers  
 4 that were in it were supposed to go to pre-market  
 5 issues, ODE. So I got transferred from that to ODE,  
 6 Office of Device Evaluation. So I know it doesn't  
 7 exist.  
 8 Q When you were working with FDA, you never had  
 9 final authority to approve a device, did you?  
 10 A I think you mean final sign-off in terms of  
 11 the letter? That's correct.  
 12 Q Correct.  
 13 A That is a chain of command that -- that is  
 14 correct. I didn't sign -- did I have the authority to  
 15 approve and deny? Yes, but not the final signoff.  
 16 Q And you never had responsibility for approving  
 17 a drug label, did you?  
 18 A A drug label?  
 19 Q Um-hum, or a medical device label, final  
 20 authority.  
 21 A I did as a clinician. If I didn't approve it,  
 22 it wasn't going to get approved, but I didn't sign the  
 23 letter. I agree, I did not sign the final letter.  
 24 That's an administrative point of view.

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1 are you?  
 2 A That's correct. The cell phones -- actually,  
 3 there were cell phones at that time. You weren't given  
 4 a cell phone by the FDA. Is that what you're talking  
 5 about?  
 6 Q No, I'm just asking -- I'm asking if you or  
 7 anyone of your colleagues at FDA carried around a cell;  
 8 phone.  
 9 A Yeah, in those days cell phones existed,  
 10 because we had safety issues and health risk assessments  
 11 that I sat in, because that --  
 12 Q I'm not asking if they existed. Move to  
 13 strike as nonresponsive.  
 14 I'm asking if you or any of your colleagues at  
 15 FDA carried around a cell phone, yes or no.  
 16 A I don't recall.  
 17 Q Okay.  
 18 A I don't recall. But I knew that they existed.  
 19 Q You worked in the Office of Health Affairs?  
 20 A Originally, the first two years with the  
 21 Office of Health Affairs, yes, at CDRH.  
 22 Q Do you know, would that be the OHA?  
 23 A Yes, sir.  
 24 Q Do you know if it's still an office within the

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1 Q Has FDA ever asked your opinion about labeling  
 2 since you left in 1995?  
 3 A Yes, they have. They had me go as an expert  
 4 on their panel about device labeling.  
 5 Q And when was that?  
 6 A 1997. They were trying to have an advisory  
 7 panel to discuss ways of improving medical device  
 8 labeling to make it more consistent, like drug labeling.  
 9 Q And is 1997 the last time?  
 10 A Yes, sir.  
 11 Q When you worked with the FDA, did you work  
 12 with any type of mesh products?  
 13 A I don't recall, because mesh products -- I had  
 14 a lot of surgical products I don't recall. I mean --  
 15 Q You don't recall being involved with any type  
 16 of SUI products at FDA?  
 17 A I don't recall because I was also the medical  
 18 officer for the urological and I also supported the  
 19 OB-GYN, so I'm not sure, and occasionally I would  
 20 consult for plastic surgery. So I don't know if that  
 21 would cover all the places where they would come.  
 22 Q At FDA, you were never involved with any type  
 23 of pelvic floor repair products, were you?  
 24 A I don't believe I was.



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1 Q At FDA, you were never involved with Prolene.  
 2 A That's not true.  
 3 Q Okay.  
 4 A I actually had to go look at the NDA for  
 5 Prolene for suture issues, because it was a transitional  
 6 device, so I have looked at the NDA through the  
 7 510(k)'s. So I was involved --  
 8 Q For what reason?  
 9 A Oh, wait, I was involved with mesh being used  
 10 for vascular grafts. So I did have to get involved with  
 11 mesh, because -- it was mesh and other things.  
 12 Q But I'm talking about any type of mesh for SUI  
 13 products. You've not been involved at FDA with any type  
 14 of mesh used for SUI products, is that correct?  
 15 A That's correct, because they actually came on  
 16 the market after I left, pretty much.  
 17 Q Why did you look at the NDA for Prolene?  
 18 A There were issues on suture, and so you had to  
 19 go back to the NDA. I don't recall why, but I remember  
 20 having to look at the Prolene NDA, which was over in  
 21 CDER and going through it, and since I've been involved  
 22 in litigation stuff, too, I've looked at suture and  
 23 Prolene, so.... But it began at the FDA.  
 24 Q Okay. At FDA, did you ever work with J&J or

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1 Q When?  
 2 A That would have been -- it's on my CV. That  
 3 would have been -- I don't remember the years. It was  
 4 early after I left FDA, Johnson & Johnson came and found  
 5 me, because I had been involved in an issue, a device,  
 6 kind of a device/drug issue, and so they asked me to  
 7 write a letter to the internal -- to an internal  
 8 medicine journal about my involvement as an FDA medical  
 9 officer looking at their product, and they also had me  
 10 write an article on the workup of preservatives in terms  
 11 of drugs and devices, and then I taught at their  
 12 national sales meeting one year. I have a clock from  
 13 Johnson & Johnson saying thank you for my help. So yes,  
 14 I did work for Johnson & Johnson.  
 15 Q You didn't consult with Johnson & Johnson  
 16 about any mesh product, did you?  
 17 A Not for surgical mesh product, that's correct.  
 18 Q At FDA, you were never responsible for  
 19 post-marketing surveillance of a medical device?  
 20 A Well, no, I was involved with post-market.  
 21 That was with the OHA.  
 22 Q With a medical device.  
 23 A All medical devices, in terms of looking at  
 24 the accuracy of warnings, instructions for use. I was

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1 Ethicon?  
 2 A Yes.  
 3 Q Okay, on what?  
 4 A They were -- they have a lot of medical  
 5 devices, and I also was involved with them after I left  
 6 FDA, but in terms of, one of the issues was I think a  
 7 product called Interceed that I was called in to as a  
 8 chief medical officer to sit in a meeting that the  
 9 company was selling a product with claims that weren't  
 10 accepted to the FDA. So I had to work, trying to bring  
 11 Interceed under -- in compliance with the requirements  
 12 of the Act.  
 13 Q Would -- could -- but when you were working at  
 14 FDA, you never worked with J&J or Ethicon regarding any  
 15 mesh product, correct?  
 16 A Well, that's an abdominal adhesion product  
 17 that's similar, but it's not --  
 18 Q I'm talking about a mesh product for SUI.  
 19 A Well, that's different. No, I wasn't involved  
 20 in -- Johnson & Johnson, and then I was involved with  
 21 Johnson & Johnson when I left FDA, I worked with them as  
 22 a consultant.  
 23 Q When, with Johnson & Johnson?  
 24 A Yes, sir.

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1 actually on a post-market surveillance, or -- the head  
 2 of post-market surveillance for anesthesia products.  
 3 So yeah, that was what I did in OHA was  
 4 post-market and all, and I would report to the Office of  
 5 Compliance. I think that's where Tim Hulatowski was, in  
 6 Office of Compliance. I was their medical support,  
 7 because at that time they didn't have MDs.  
 8 Q When was the first time you'd ever heard of  
 9 TVT Secur?  
 10 A TVT Secur, I really hadn't heard about TVT  
 11 Secur until I was asked to be involved with TVT Secur.  
 12 I had been involved with TVT and TVT-O in terms of all  
 13 the other products, and I was aware of the clearance of  
 14 it, I believe, in the '95 period, TVT, and so --  
 15 Q You were contacted -- strike that.  
 16 A In August, I believe.  
 17 Q In August of 2014.  
 18 A Correct, about TVT Secur. I may have focused  
 19 on the others.  
 20 Q Have you ever seen a TVT Secur device?  
 21 A Now I have, in terms of the pictures.  
 22 I haven't physically held one.  
 23 Q Do you understand the procedure for implanting  
 24 a TVT Secur device?

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1 A I don't think anybody does, but --

2 Q Let me ask you this: Do you agree that you do

3 not have the requisite education, training and

4 experience to implant a TVT device, a TVT Secur device?

5 A I would agree with that. I would agree with

6 that for the entire -- I don't have -- to physically

7 implant it in a patient, I would not even attempt it.

8 And so I agree that I would not even attempt it, and

9 that's not my role, and that -- FDA people don't have

10 that training, either.

11 Q Do you know the difference between

12 polypropylene and Prolene?

13 A Well, polypropylene is the material that

14 Prolene mesh is made out of. It's a polypropylene mesh

15 that can vary in terms of -- well, polypropylene, yeah,

16 that's the answer.

17 Prolene can be a suture, and resin -- it's a

18 resin. Polypropylene is a resin that's used to make

19 whatever they need in terms of suture or mesh or what's

20 ever made up of; it's called Prolene, and the trade name

21 is Prolene, at Ethicon.

22 Q My question to you, though, is: Do you know

23 the difference between polypropylene and Prolene?

24 A Yes, Prolene is --

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1 Q What is the difference?

2 A Prolene is the trade name. Polypropylene is

3 the type of resin that's used to make whatever product

4 is going to be named Prolene.

5 Q Do you know -- what do you know about the

6 manufacturing process Ethicon uses to make Prolene?

7 A Well, it's usually a mesh extrusion,

8 polypropylene resin extrusion process, which you have of

9 the extruder make fibers, and then you use the fiber to

10 weave what you need to do in terms of your mesh.

11 So that's it basically, and then once you've

12 made your fibers to your diameter and you've woven it

13 the way it's supposed to, then you have to clean it, you

14 have to sterilize it, and you put it in your kit.

15 Q And you know that mesh is made of knitted

16 filaments of Prolene sutures, don't you?

17 A Yes.

18 Q We can agree to that.

19 A Yeah. It's thread, you can think of it as

20 thread, and every mesh has its own design in terms of

21 the way it's woven, in terms of the pores and -- yes,

22 and it's multi-filament, I believe, in terms of the

23 mesh.

24 Q I know we've talked about your opinions about

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1 design defect, but do you have any manufacturing defect

2 opinions?

3 A You know, manufacturing -- let me clarify what

4 I think you mean. Manufacturing would, like a lot, did

5 I look at Ms. Garcia's lot and look and see if there was

6 an particular issue with her lot in terms of the quality

7 assurance? No, I did not look at that.

8 So I don't have any specific manufacturing

9 defect issues about the line, but I've not been asked to

10 look at all the good manufacturing practices about

11 specific lots.

12 Q Has any of your work at FDA or since then

13 involved polypropylene or Prolene, with the exception of

14 the hernia, the stuff that we talked about earlier?

15 A Yeah, I mean, AMS uses polypropylene in terms

16 of their Sparc mesh. So I've looked at the Sparc mesh

17 and the evolution of how that mesh comes out. So yeah,

18 I've done that, and Kugel, like we said, and then I've

19 looked at Bard's. I once did a case with C.R. Bard and

20 Marlex mesh. So I've looked at polypropylene mesh.

21 Q Have you ever performed any type of study on

22 the biocompatibility of polypropylene or Prolene?

23 A I haven't done any studies. I've looked at

24 toxicology data in terms of the inflammatory response

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1 that you get from different types of mesh, looking at --

2 and I've looked at more than just Prolene. I've looked

3 at the soft meshes, light meshes, heavy meshes,

4 ultra-light, all those different variations in terms of

5 your weight and the type of biocompatibility responses

6 you get for, like, hernia. I didn't do the hernia

7 issues, but the hernia meshes. So I've looked at that,

8 in terms of animal toxicology.

9 Q You've never participated in any clinical

10 trials regarding polypropylene, have you?

11 A No.

12 Q Or done any clinical research on

13 polypropylene?

14 A No.

15 Q Or you've never seen any degraded

16 polypropylene?

17 A No, I've seen that in my world of going

18 through meshes, I've seen degraded, but I've not -- I've

19 not been -- made a study of degraded mesh.

20 Q Right, but have you ever seen degraded

21 polypropylene under a microscope?

22 A I've seen -- I've seen slides of it, I mean,

23 pictures. I haven't put one under the -- I have four

24 microscopes, but I haven't put that under my microscope.

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1 Q Have you ever done any type of independent  
2 testing or analysis or any root cause analysis to  
3 determine if Prolene is defective?

4 A No.

5 Q Let's talk about Ms. Garcia for a minute. You  
6 didn't review her medical records.

7 MR. LUNDQUIST: Object to form.

8 THE WITNESS: I did review Dr. Walss'  
9 testimony, and I do have --

10 MR. HUTCHINSON: Move to strike as  
11 nonresponsive.

12 Q I'm talking about medical records.

13 A Right, and I have her progress reports and  
14 medical records in one of my folders here, so that --

15 Q Oh, I'm sorry.

16 A So you would have that.

17 Q Have you spoken to any of her doctors?

18 A No.

19 Q Do you have any idea what information  
20 Dr. Walss relied on when he was consulting with  
21 Ms. Garcia?

22 A Based his testimony, yes.

23 Q Outside of what's in his testimony?

24 A No.

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1 for erosion and that it would be transitory. He  
2 testified to -- a lot about that, and -- but he did not  
3 know that it was more than rare, and so -- we know that  
4 that's, in terms of his informed consent, he didn't use  
5 that in the informed consent because he did not think  
6 that it was something that was actually going to occur,  
7 and that it was transitory, it wasn't permanent. And he  
8 wasn't aware of having to remove it -- the frequency for  
9 failure and the removal --

10 Q Do you know -- I'm sorry.

11 A -- and the risk for dyspareunia. He wasn't  
12 aware of that, too. I'm trying to remember what else he  
13 said he wasn't aware of.

14 Q Do you know whether Ms. Garcia saw the patient  
15 brochure?

16 A She did not. I don't believe she was  
17 specifically asked at her deposition, but she did not  
18 reference having seen one.

19 Q Have you ever spoken with any doctor who has  
20 implanted a TVT Secur device?

21 A No, sir.

22 Q Have you ever talked with any doctor about the  
23 IFU for a TVT Secur device?

24 A I haven't specifically spoken to him. I have

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1 Q Do you know whether Dr. Garcia (sic) relied on  
2 the IFU?

3 A He read the IFU, so -- I have the IFU -- so  
4 yes, he did read it.

5 Q Do you have any idea of what training from  
6 Ethicon Dr. Walss may have received about the TVT Secur?

7 A All he says is that he went to a course. We  
8 don't know who presented it. He said there were other  
9 people, other devices being presented, and sales reps  
10 were there. We don't have a specific course. He said  
11 that he did have the sales rep come and watch him do  
12 several cases and say that he had -- he was doing it the  
13 way he was supposed to do it.

14 So that's in terms of his training. Then he's  
15 used the TVT and the TVT-O. That's all I can see from  
16 his depo in terms of the Secur.

17 Q And I'm sorry, I think you said Dr. Walss was  
18 using it the way he was supposed to?

19 A That's what he was told by the representative  
20 from Ethicon who watched him do a couple cases.

21 Q Do you have any idea of what potential risks  
22 of TVT Secur that Ms. Garcia's doctor was aware of?

23 A He was aware of the surgical risks of the  
24 procedure. He was aware that there could be a rare risk

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1 Dr. Miklos' report and I have Walss --

2 Q Well, what about any mesh product?

3 A Have I spoken to doctors who implanted mesh?

4 Q Yes, about the IFUs for any mesh product.

5 A No. I've seen a lot of IFUs for mesh  
6 products. I've not spoken to doctors specifically about  
7 them.

8 Q Did you do any type of study or survey of  
9 doctors to determine what risks associated with SUI  
10 surgery they're aware of?

11 A No.

12 Q Do you have any study or survey of doctors to  
13 determine what risks from the TVT Secur product that  
14 they appreciate from the IFU?

15 A We have Dr. Miklos, and Doctor --

16 Q Other than the plaintiff's expert.

17 A -- we have Dr. Walss, and he's relevant to  
18 Ms. Garcia, and so he wasn't -- he goes on about the  
19 things that he wasn't aware of, in terms of the IFU.

20 Q But no study or survey of doctors, correct,  
21 that you've done?

22 A That I've done, no, I haven't done a study.

23 Q You've never drafted a label or IFU for a mesh  
24 device, have you?

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1 MR. LUNDQUIST: Form.

2 THE WITNESS: I don't recall, because the FDA  
3 doesn't draft the labels, they look at the labels, but  
4 I don't recall if any of the PMAs actually had a --

5 BY MR. HUTCHINSON:

6 Q Or any types of SUI device.

7 A For an SUI device, I did work with a  
8 manufacturer that I did help draft the labels as a  
9 consultant for that, and I evaluated their data.

10 Q And what manufacturer was that?

11 A I think it's INSURx, I-N-S-U-R-X, and it was  
12 that they had gotten rejected by the FDA on their  
13 clinical data and I was brought in to go over the  
14 clinical data to kind of reorganize it, reevaluate and  
15 then it got cleared.

16 Q And that was with -- I'm sorry, INSURx?

17 A I believe that's what the name was,  
18 I-N-S-U-R-X. I was brought in by another consulting  
19 firm, Weisbrod, I think -- not Weisbrod, Weisberg. It  
20 was a consulting firm in Washington, D.C. I don't  
21 remember their name. Anyway, they needed someone who  
22 could go through the clinical data.

23 Q You've never drafted patient brochure for a  
24 mesh device, have you?

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1 labels for the FDA? It's not a committee. Because,  
2 see, drug does have that, the CDRH doesn't have that.  
3 Yes, I've sat on safety issues in the sessions about  
4 labels and warnings.

5 Q Have you ever designed any label readability  
6 studies?

7 Label readability studies, for the court  
8 reporter.

9 A Readability. I actually consulted for the  
10 division in CDRH that was doing that when they were  
11 trying to develop home health products, and so I was the  
12 medical input as to their readability. I didn't design  
13 the study.

14 Q You've never talked with FDA about the  
15 regulatory history about the TVT Secur, have you?

16 A No.

17 Q Do you intend to offer what the -- the actual  
18 verbiage, do you intend to offer opinions about what the  
19 actual verbiage of the IFU should say?

20 A Yeah, I could do that. And which IFU? They  
21 only that had one IFU for the Secur, so yeah, I can talk  
22 about the verbiage, what's missing.

23 Q That's what I want to ask you about. I'm  
24 going to hand up what I'll mark....

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1 A For a mesh device, no, that is correct.

2 Q Yes, ma'am, or for an SUI device?

3 A Well, I worked on their device, but --

4 Q I'm talking about a patient brochure.

5 A Yeah, they had a patient brochure.

6 Q Have you ever consulted with the FDA about an  
7 SUI mesh device?

8 A Consulted for -- specifically, no. Well,  
9 I did consult for this company that went into the FDA  
10 and got cleared. I didn't go to the meetings with the  
11 FDA, that I recall.

12 Q And what product was this INSURx trying to  
13 bring to market?

14 A It was a radiofrequency device that's used for  
15 treating the woman's vagina, urethra, so that you would  
16 decrease SUI. It was just an alternative treatment,  
17 sort of like they use Botox when you're thickening the  
18 tissue.

19 Q But it didn't have any mesh in it.

20 A No mesh, no mesh.

21 Q You've never sat on a FDA warnings or label  
22 committee, have you?

23 A I don't know what that would be. I mean, have  
24 I sat on committees where you talk about warnings or

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1 What's the next exhibit?

2 (Whereupon, Exhibits 6 and 7 were marked  
3 for identification.)

4 BY MR. HUTCHINSON:

5 Q Dr. Parisian, I'm handing you what I'm marking  
6 as Exhibit 6 and Exhibit 7 to your deposition.

7 A Okay.

8 Q And Exhibit 6 is the IFU and Exhibit 7 is the  
9 patient brochure. Does that look right?

10 A No, this is the later one. This is 2011. Her  
11 surgery was 2012. I looked at 2008. Yes, I think it  
12 is, okay.

13 Q Let's look at Exhibit 6 now.

14 A I'm also pulling up Dr. Miklos, because he  
15 also talked about what he thought --

16 Q Well, I don't want to talk about Dr. Miklos.  
17 I want to talk about your opinion. So let's look at  
18 Exhibit 6.

19 A Okay, but I can pull it up.

20 Q Did you review Exhibit 6 in forming your  
21 opinions?

22 A Yes, sir.

23 Q What criticisms do you have about the IFU that  
24 was marked as Exhibit 6?

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1 A Okay. Is this the order that it really is in?  
 2 Yeah. One of the criticisms is that the information  
 3 about risk and benefits and all should be up front.  
 4 They're showing the procedure, so like, if you're a  
 5 physician, you're going to be -- more likely it's going  
 6 to be the procedure, to look at the procedure, not look  
 7 at the IFU.

8 Q Right.

9 A So right away, that downplays the IFU  
 10 information, which --

11 Q Okay, what else?

12 A -- which increases the need for the company to  
 13 communicate through its sales reps or through Dear  
 14 Doctor letters, is typically the design of that, and  
 15 what you --

16 Q So I'll tell you what, Dr. Parisian. Help me  
 17 make a list, please. I want to know what all criticisms  
 18 you have of the IFU marked as Exhibit 6.

19 Number one, I have information regarding risk  
 20 and benefits should be up front, correct?

21 A Right, it's on page 10.

22 Q And what's your second criticism?

23 A Okay, let me tell you. Again, the  
 24 positioning. They have the description --

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1 asking about what your opinion is, about what the --  
 2 what your criticisms are about the IFU.

3 A And I'm telling you.

4 Q Okay.

5 A The placement of it, the --

6 Q The placement of the description --

7 A No, no.

8 Q -- on page 10?

9 A No, no, no. The placement of the important  
 10 information for the IFU is actually -- and we're up to  
 11 page 10, and you've got this long description that no  
 12 surgeon is going to sit there and want to read --

13 Q Okay, so --

14 A -- about polypropylene mesh and all this  
 15 stuff, and --

16 Q So you believe that the information on page 10  
 17 should be moved to the beginning of the IFU; is that  
 18 what your testimony is?

19 A No.

20 MR. LUNDQUIST: Form.

21 BY MR. HUTCHINSON:

22 Q Then where should it be moved?

23 A That's what -- I'm looking at the label and  
 24 I'm going to tell you what's going to be moved. In

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1 Q I'm sorry?

2 A The positioning of it.

3 Q The positioning of what?

4 A Of the label. They have it --

5 Q Of what on the label?

6 A I'm going to tell you.

7 Q Okay.

8 A They have, under Description, they have this  
 9 long description of the polypropylene mesh, its  
 10 filaments. Doctors aren't going to read that. It's got  
 11 to be up front.

12 Q What page are you on?

13 A I'm on page 10. You're putting stuff that a  
 14 physician who's implanting this is not going to care  
 15 about.

16 Q All right. So let me ask you this, and make  
 17 sure we're clear: That what you suggest is that the  
 18 wording on page 10 under Description should be up front,  
 19 correct?

20 A No.

21 Q All right, help me out.

22 A I'm saying that the way this is written about  
 23 the -- in terms of physicians --

24 Q No, I'm not asking about physicians, I'm

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1 terms of -- you've already the lost the physician. He's  
 2 not going to read any of this stuff.

3 Q Move to strike as nonresponsive. I'm asking  
 4 you, where should --

5 A I'm going to tell you what needs to be moved,  
 6 okay?

7 Q -- it be moved?

8 A Hold on. All this is surgical stuff. When  
 9 you see the contraindications, warnings and precautions,  
 10 you should have that up front. It's now on page 20, so  
 11 we're 10 pages back from where anything begins --

12 Q Move strike as nonresponsive. I'm asking you,  
 13 where --

14 A I'm telling you.

15 Q -- the information on page 10 should be moved  
 16 in the IFU?

17 A It should be moved to after -- it should be  
 18 shortened, for one thing. The description should be  
 19 just that little part up there, the first part, and then  
 20 you should have --

21 Q I'm not asking how it should be shortened or  
 22 how it should be lengthened. I'm asking where it should  
 23 be moved.

24 A It should be front, the first page.

<p style="text-align: right;">Page 130</p> <p>1 Q Okay, so you're telling me that the</p> <p>2 information on page 10 should be moved to page 1,</p> <p>3 correct?</p> <p>4 A Yes.</p> <p>5 Q Okay.</p> <p>6 A And it should be -- because the device -- it's</p> <p>7 describing what the device is, and then the next thing</p> <p>8 that should come is the indication for use.</p> <p>9 Q All right, so the criticisms that I have is,</p> <p>10 number one, the information regarding risk and benefits</p> <p>11 should be up front instead of page 10; the second</p> <p>12 criticism I have is the placement of important</p> <p>13 information on page 10 should be moved to page 1.</p> <p>14 What other criticisms, if any, do you have</p> <p>15 about the IFU?</p> <p>16 A Well, the device description is so long, it's</p> <p>17 not telling the doctor what he needs to know. He needs</p> <p>18 to know what's up in that first description. He doesn't</p> <p>19 need to know all this stuff about the sandwich-bonded</p> <p>20 thermal -- doctors don't care about that.</p> <p>21 Q All right. So, Doctor --</p> <p>22 A Okay, then you have the --</p> <p>23 Q -- Dr. Parisian, stay with me. So you're</p> <p>24 testifying that the information on page 10 under</p>	<p style="text-align: right;">Page 132</p> <p>1 description of what the device should have in it. Then</p> <p>2 you have the indications for use, which is the important</p> <p>3 thing, what is it intended for. Then you go into the</p> <p>4 instructions for use --</p> <p>5 Q All right, well, Dr. Parisian, stick with me.</p> <p>6 So we're talking about your criticisms, and I have three</p> <p>7 so far. I'm sorry, I have four.</p> <p>8 I have information regarding risk and benefits</p> <p>9 should be up front instead of page 10. The second one</p> <p>10 is, important information on page 10 should be moved to</p> <p>11 page 1. Third is, too long device description on</p> <p>12 page 10; and the fourth criticism I have is that we</p> <p>13 shouldn't discuss the sandwich -- the section of the end</p> <p>14 of the mesh, on page 10.</p> <p>15 Anything else?</p> <p>16 A Yeah. All those --</p> <p>17 Q What else?</p> <p>18 A All those pictures, 1 through 10, should be</p> <p>19 under the Instructions For Use.</p> <p>20 Q Okay, I'm sorry, you're saying the pictures on</p> <p>21 pages, actually, 2 --</p> <p>22 A Right.</p> <p>23 Q -- through 8 should be somewhere else, is</p> <p>24 that correct?</p>
<p style="text-align: right;">Page 131</p> <p>1 Description is too long, correct?</p> <p>2 A Yes.</p> <p>3 Q And Dr. Parisian --</p> <p>4 MR. LUNDQUIST: Sorry, she was about to write</p> <p>5 on the exhibit. I was just making sure.</p> <p>6 BY MR. HUTCHINSON:</p> <p>7 Q And you're testifying also that the</p> <p>8 information about the sandwich sections -- I'm sorry --</p> <p>9 the information about the sandwich that ends the section</p> <p>10 of the mesh should not be included in that, correct?</p> <p>11 A Not there, the way --</p> <p>12 Q I'm sorry, is that correct?</p> <p>13 A Not -- yes.</p> <p>14 Q All right.</p> <p>15 A Because when you design a label, you want to</p> <p>16 have the information up front, so that the most</p> <p>17 important information is available to a physician.</p> <p>18 Chances are that your marketing and your sales rep is</p> <p>19 going to have to convey this information, but if you're</p> <p>20 going to make an effective IFU, you put the most</p> <p>21 important information up front. I don't think there's a</p> <p>22 physician around who would care about how this is</p> <p>23 knitted and -- that doesn't make any sense to them.</p> <p>24 They think it's a cleared device. They have here the</p>	<p style="text-align: right;">Page 133</p> <p>1 A Yeah, they have no business being up front.</p> <p>2 They should be under Instructions For Use, because</p> <p>3 they're relevant to the different positions, the</p> <p>4 U-position and the H-position. Without a picture, it's</p> <p>5 really bad instructions.</p> <p>6 Q You do understand that I've handed you what</p> <p>7 was marked as Exhibit 6 to be the Instructions For Use</p> <p>8 of TVT Secur.</p> <p>9 A I know, but they're not designed correctly.</p> <p>10 Now I see why people talk about cookbooks.</p> <p>11 Q So the pictures are not designed right?</p> <p>12 A No, the pictures are in the wrong place.</p> <p>13 Q Pictures wrong place, okay.</p> <p>14 A They should be under the Instructions For Use,</p> <p>15 where you're talking about the specific procedure, the</p> <p>16 U-procedure, the hammock procedure. You have to have</p> <p>17 pictures in the right section.</p> <p>18 Q Do you have any other criticisms --</p> <p>19 A Yeah, yeah.</p> <p>20 Q -- of the IFU?</p> <p>21 A Okay, so we have -- we started out with the</p> <p>22 Description and the Indication For Use. Then we would</p> <p>23 have, after that we would have, before you started into</p> <p>24 the Instructions For Use, you would start with the</p>



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1 contraindications, because a physician needs to know up  
 2 front what's the contraindications. That should be up  
 3 in the first --  
 4 Q I'm sorry, contraindications?  
 5 A Yeah.  
 6 Q Should be where?  
 7 A Right up after the Indications For Use.  
 8 Q Contraindications should be where, after...?  
 9 A Indications For Use.  
 10 Q On what page?  
 11 A They should be probably be out on page 1 or 2.  
 12 Q Contraindications should be on page 1, is that  
 13 correct?  
 14 A Well, it should follow the Indications For  
 15 Use.  
 16 Q I'm asking you, where should contraindications  
 17 be located?  
 18 A Well, you can't know what page, because we've  
 19 moved the Description, we've shortened it. So we've  
 20 taken --  
 21 Q Contraindications should be up front?  
 22 A Yeah --  
 23 Q Okay.  
 24 A -- after the Indications For Use, you should

Page 135

1 have the contraindications.  
 2 Q And where is contraindications now?  
 3 A It's on page 20.  
 4 Q Okay. So it should be up front rather than on  
 5 page 20, correct?  
 6 A Yeah, in the contraindications.  
 7 Q Do you have any other criticism?  
 8 A Well, yeah, I do. Just let me look at the  
 9 contraindications... (Deponent reading document.)  
 10 That contraindication comes from surgical mesh  
 11 Prolene.  
 12 Q I'm not asking where that contraindication  
 13 came from. I'm asking you about your criticisms.  
 14 A Okay, I'll tell you what my  
 15 contraindications --  
 16 Q I'm not talking about your contraindications.  
 17 I'm talking about your criticisms --  
 18 A I'm going to tell you.  
 19 Q -- of the IFU, in Exhibit 6.  
 20 A Okay, the company says to the FDA that you can  
 21 only use this product in certain selected patients. So  
 22 if there's a patient that should not be appropriate for  
 23 this product, say, weight, if the woman is too obese, it  
 24 could be in the contraindications, it could be in the

Page 136

1 warnings and precautions, but who this product shouldn't  
 2 be used for, anyone with an allergy to polypropylene,  
 3 there are patients with that, they should not also be in  
 4 here.  
 5 Q So your opinion is that the contraindications  
 6 are poorly worded, correct?  
 7 A Well, no, they're not complete.  
 8 Q Not complete.  
 9 A If the company knows of people that should not  
 10 be implanted, that would be where you would put this  
 11 information. And they're implying to the FDA, and to --  
 12 in the discussion of Australia, that they know that  
 13 there are patients that this product is good for and  
 14 not.  
 15 Q What should the contraindications have  
 16 included that they don't include already?  
 17 A Well, the 8 centimeters mesh was chosen  
 18 because it would fit most patients. So if it doesn't  
 19 fit most patients -- this isn't a two-size device, it's  
 20 a one-single-size device -- that would be in the  
 21 contraindications.  
 22 Q Okay.  
 23 A If a woman that's too obese, or -- what woman  
 24 is contraindicated, what --

Page 137

1 Q What other criticisms do you have about the  
 2 IFU?  
 3 A Well, we're still -- so the contraindication  
 4 if a person has an allergy to polypropylene, there are  
 5 people that do, then that would be contraindicated in  
 6 that patient --  
 7 Q Okay.  
 8 A -- and --  
 9 Q So my question to you is, what other  
 10 criticisms of the IFU do you have?  
 11 MR. LUNDQUIST: She hasn't finished answering  
 12 your question, I don't think, on contraindications.  
 13 Have you?  
 14 THE WITNESS: Right. So if the  
 15 contraindications --  
 16 MR. HUTCHINSON: No, she testified that the  
 17 contraindications are incomplete.  
 18 THE WITNESS: All right, and that they should  
 19 be addressed.  
 20 Okay, the Warnings and Precautions is now what  
 21 we're going through. At this time --  
 22 BY MR. HUTCHINSON:  
 23 Q My question is: What are your criticisms  
 24 about the Warnings and Precautions? Is it the placement



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1 or is it the verbiage, or language?

2 A Well, all -- we're talking about, okay, the

3 placement. This should be up front, on page 1 or 2, not

4 page 20.

5 Q Okay.

6 A Okay, let me look at the warnings. Okay, they

7 have a statement under Warnings and Precautions,

8 "Users should be familiar with surgical

9 technique for urethral suspension and should

10 be adequately trained in the Gynecare TVT

11 Secur system before using."

12 I've criticized that they don't have a

13 certification, so how would a physician out there

14 adequately train to use it? All they're saying is that

15 you have to know how to use -- do urethral surgery.

16 Dr. Walss did a lot of urethral surgery.

17 Q Move to strike as nonresponsive.

18 A Well --

19 Q We're not talking about Dr. Walss.

20 A No --

21 MR. LUNDQUIST: She's answering your question.

22 BY MR. HUTCHINSON:

23 Q So my question is: What other criticisms do

24 you have about the IFU?

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1 A It defines -- it should define what would be

2 someone who's adequately trained. Would it be someone

3 who would go to a course? Would it be -- you know, and

4 so their marketing should be consistent with that, that

5 those people who were adequately trained, by definition

6 here, then should use this product. That would be a

7 warning.

8 Q What else? What other criticisms do you have?

9 A The second, that it should be used with care

10 to minimize the chance of damage to large vessels,

11 nerves, bladder and bowels --

12 Q I'm sorry, is this the language?

13 A No, no, this is -- I'm just showing you where

14 I am.

15 Q I know, but you're reading a document.

16 A Right.

17 Q My question is: What criticism do you have

18 about the IFU?

19 A Well --

20 Q And I'm making a list. So what is the next

21 one on our list?

22 A We're moving to the next one, where they're

23 saying that it is important to pay attention to the

24 specific patient's anatomy while inserting the device.

Page 140

1 Q Okay, so is that --

2 A That's a --

3 Q Is that a criticism you have about the

4 language under the warnings?

5 A Yeah.

6 Q Okay.

7 A That's a real stupid statement.

8 Q Anything else?

9 A I mean, to a physician, that means nothing,

10 I mean. And also, you don't say that the device, unlike

11 the other devices, is sharp. So it does have a tendency

12 to cut.

13 Q So other than a criticism of language in the

14 warnings, do you have any other criticisms of the IFU?

15 A No, I'm still going, looking at -- we're

16 looking at Warnings and Precautions.

17 Q Well, you've already criticized the language,

18 I get that, but other than the criticisms of the

19 language and the warnings, do you have any other

20 criticism of the IFU for TVT Secur?

21 A I think they tell them, for the hammock

22 position, that bladder injury is unlikely, but --

23 Q Where are you?

24 A I'm moving down the warnings, under the

Page 141

1 "hammock" position.

2 Q Okay, and that goes to the language, correct?

3 A Well, no, no. It's -- this is a warning,

4 okay? And so for the hammock position, the hammock

5 position is the most commonly used position and also the

6 one that's getting reported with bladder perforation.

7 Q What's your criticism about that, the

8 language?

9 A Well, no, it doesn't give the post-market

10 information about the bladder perforation rate.

11 Q Okay.

12 A Because it's one thing to say that it's

13 unlikely to occur with this technique, but bladder

14 perforation is actually being reported, I think, in some

15 documents, at 19 percent. So that information

16 underplays the potential risk to a physician on the

17 hammock position.

18 Q All right.

19 A And then the hammock position, as we saw also,

20 if the device isn't put near the pubic bone, you may

21 actually hit blood vessels, which was another thing that

22 was there. So if you're going to talk about the risk of

23 the hammock position, you need to say those.

24 Q Do you have any other criticisms --

Page 142

1 A Yes.

2 Q -- about the IFU?

3 A Now, they're saying, "Ensure that the tape is

4 placed with -- "

5 Q I'm asking you, do you have any criticisms

6 about the IFU?

7 A Yes.

8 Q Okay.

9 A I'm telling you what.

10 Q What's the next criticism?

11 A Based on the information they have, this is

12 not a good IFU. They also --

13 Q What's your criticism?

14 A I'm going tell you, "Ensure the tape is placed

15 with -- "

16 Q You're just reading from a document.

17 A No, I'm --

18 MR. LUNDQUIST: She's giving the basis for

19 her --

20 THE WITNESS: I'm trying to tell you where I

21 am, why it's wrong.

22 BY MR. HUTCHINSON:

23 Q I meant, what's your criticism?

24 A You're telling a physician, under Warnings and

Page 143

1 Precautions, that there should be no tension placed

2 under the mid-urethra.

3 Q And you believe that's wrong.

4 A I believe that's wrong and inaccurate, in

5 terms of their internal documents, when they say

6 tensioning is very important in terms of this device,

7 and so this is not an adequate warning.

8 I mean, these are warnings. Warnings are

9 like, red light, yellow light, important information,

10 and this is not -- this is not telling them that

11 tensioning is very important to the success of this

12 procedure; and you see that through all their documents,

13 and that information's not there, and --

14 Q What other criticisms do you have,

15 Dr. Parisian, of the IFU?

16 A The other is that there is nothing here about

17 the learning curve. All the documents internally are

18 discussing the long learning curve --

19 Q And so let me ask you this: Is your opinion

20 that there should be something in the IFU that says

21 there's a long learning curve?

22 A Yeah.

23 Q Okay.

24 A Because they're talking --

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1 Q And -- hold on just a minute, stick with me.

2 What other opinions do you have, or criticisms, rather,

3 about the IFU?

4 A Okay, I'm talking -- these are warnings, and

5 so the learning curve should actually go up where

6 they're talking about, the physician should be aware of

7 the surgical technique and adequate training. Okay,

8 then, you would put the learning curve in there. These

9 are warnings. Warnings are supposed to be, before you

10 use this, Doctor, you need to know this.

11 Q Stick with me. So what other criticisms do

12 you have?

13 A The next statement, "Acceptable surgical

14 practice should be followed," that's not a warning.

15 Doctors know that.

16 Q And so that shouldn't be in there, correct?

17 A "...should be followed -- "

18 Q Is that correct?

19 A Let me look at it. As well -- I mean, yeah,

20 that's not a warning, because doctors would think of

21 that just in terms of surgical stuff. What should be

22 there is the potential for these things to be

23 contaminated and difficult to remove. That's a better

24 warning. Here, this is just telling a doctor he needs

Page 145

1 to know how to do surgery technique. That's not a

2 warning.

3 Q Which bullet point are you?

4 A I'm on the first one on page 21.

5 Q Okay. All right, the acceptable surgical

6 practice. All right, any other criticisms?

7 A Well, the next one, do not perform this if you

8 think the surgical site may be infected. You're talking

9 about the urethra and the woman's vagina, which is

10 contaminated --

11 Q So you don't like the bullet point -- you

12 don't like the language in bullet number 2 on page 21,

13 correct?

14 A Correct.

15 Q All right, any other criticisms?

16 A Okay, so they do mention removal --

17 Q Doctor --

18 A No, I'm continuing on that --

19 Q Do you have any other criticisms of the IFU?

20 A Yes, yes.

21 Q Okay. What are they?

22 A Okay, where they're talking about the surgical

23 site, they're saying that it must only be with the

24 understanding that subsequent infection may require its

Page 146

1 removal. Actually, the tape has been removed for many  
2 reasons. So this would be where you would highlight the  
3 risk of infection, the potential removal, a need for  
4 additional surgical procedures, and it could be  
5 difficult to remove and you actually may never be able  
6 to treat the infection.

7 So you have, the risk of infection could be a  
8 permanent issue, you may not be able to remove the  
9 surgical mesh, and it may be something that could cause  
10 problems forever. So that doesn't convey that.

11 Q All right. Do you have any other criticisms?  
12 I'm making a list about what -- hold it just a minute,  
13 Dr. Parisian. Listen to my question. I'm making a list  
14 and I'm up to 15 now criticisms that you have for the  
15 IFU. Does that sound about right so far?

16 A Yeah, I'm going through the IFU with you --

17 Q Okay.

18 A -- we're all the way through, you --

19 Q I know, but does that sound right so far? You  
20 have at least 15 criticisms of the IFU so far?

21 A Yeah.

22 Q Okay.

23 A It's not -- it's got a good IFU.

24 Q Okay, if you could continue.

Page 147

1 A All right.

2 Q What's your next criticism of the IFU?

3 A I don't know why they put the pregnancy there.

4 Q Is that a criticism?

5 A You could actually put a pregnancy as a one  
6 single line. Yeah, this is --

7 Q All right. My question is, is that a  
8 criticism?

9 A Yeah.

10 Q Okay, so we're up to 16?

11 A Yeah.

12 Q Okay.

13 A But see, in terms of warnings, you're supposed  
14 to put the most important things first. It's not likely  
15 that this is going to be used on a pregnant woman,  
16 but --

17 Q What other criticisms do you have about the  
18 IFU?

19 A I'll go on. There's again, pregnancy, women.  
20 You could have just put pregnancy off by itself as a  
21 separate population, because it's not going to be what a  
22 physician who's potentially going to be doing this is  
23 thinking about. You could have had a special population  
24 and had pregnancy under that, considerations for

Page 148

1 pregnancy. That would -- let's see...

2 Okay, the next is just a routine warning for  
3 surgical procedures.

4 Q Is that a criticism you have?

5 A Yeah.

6 Q Okay, so is that 17 criticisms?

7 A This would just be --

8 Q Doctor -- Dr. Parisian --

9 A I don't know if would be or not, but you would  
10 use --

11 Q Okay. Dr. Parisian --

12 A Yes.

13 Q Are we up to 17 criticisms you have for the  
14 IFU?

15 MR. LUNDQUIST: Object to form.

16 THE WITNESS: I don't know. You're keeping  
17 track. I wouldn't argue with you, but --

18 BY MR. HUTCHINSON:

19 Q Well, if I've counted to 17 criticisms you  
20 have of the IFU, would you have any reason to dispute  
21 that?

22 A No, sir.

23 Q Okay.

24 A The other is that --

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1 Q What's number 18?

2 A Number 18 would be that the postoperative  
3 should be under the Instructions For Use, not under the  
4 Warnings and Precautions, because that would be  
5 postoperative information that you would tell your  
6 patient about, not to jog. So it doesn't need to be in  
7 the Warning and Precautions, it needs to be under the  
8 Instructions For Use and the postoperative course.

9 Q Okay.

10 A It's just in the wrong place.

11 Q What's number 19?

12 A Okay, and the same with, "Patient should be  
13 instructed to contact surgeon," that should be under  
14 postoperative care and instructions for use.

15 Q All right, what's number 20? What's  
16 number 20, Dr. Parisian?

17 A I'm looking. The next talks about de novo  
18 destrutor stability.

19 Q And what's wrong with that?

20 A There's no information as to how frequent, and  
21 yet they're trending it in their own post-market  
22 information. So how frequently does that occur for this  
23 device, in terms of a meaningful warning for a  
24 physician?

Page 150

1 Q What's number 21?

2 A Twenty-one, we'll leave that --

3 Q What's your 21st criticism of the IFU?

4 A Well, in terms of the IFU, in terms of

5 Warnings and Precautions, the information that needs to

6 be in there that's not in there, because I've gone

7 through the information that is, should be the failure

8 rate. What is the likelihood of the failure rate, based

9 on tensioning, inadequate tensioning --

10 Q Is that -- I'm sorry.

11 A That's not in the warnings at all.

12 Q Is that your 21st criticism?

13 A Yes, sir.

14 Q Okay. What would be the -- do you have any

15 other criticisms of the IFU?

16 A I don't think the number really applies,

17 because we're talking about a redesign of a label that's

18 inadequate.

19 Q What is your next criticism of the IFU,

20 Dr. Parisian?

21 A Let me think about it. Let me think about it.

22 Okay, you need to include the failure rate that

23 they've --

24 Q I'm sorry, the failure rate?

Page 151

1 A Yes.

2 Q Doctor, Dr. Parisian, you're talking real fast

3 on me. Including the failure rate, would that be the

4 22nd criticism you have of the IFU?

5 A Yeah, there's no information in here about the

6 high failure rate that's being seen in the post-market

7 information.

8 Q Do you have any other criticisms of the IFU?

9 A Let me think. I'm thinking. Actually,

10 I think that I would have divided this label differently

11 in terms Warnings and Precautions, because medically --

12 drugs had combined warnings and precautions in 2006, but

13 not medical devices.

14 So there should be a hierarchy of warnings

15 versus precautions, because warnings would be your

16 higher risk information, like, do not use an

17 anticoagulation therapy, that first one, that's a

18 warning, whereas a precaution -- putting them together

19 doesn't give a doctor....

20 So the way they've categorized -- you can make

21 it 20 whatever-it-is -- the warnings and the precautions

22 should be separated, because warnings are of higher risk

23 to a physician implanting the device and it needs to be

24 highlighted. It wasn't combined in medical devices, it

Page 152

1 was combined in drugs.

2 Q Dr. Parisian, your -- what is your -- your

3 24th criticism was to divide the label differently.

4 What is your 25th criticism, though --

5 MR. LUNDQUIST: Form.

6 BY MR. HUTCHINSON:

7 Q -- of the IFU?

8 A Okay, but I wanted to make it clear for you,

9 I'm talking about -- we just went through Warnings and

10 Precautions. I'm not going to go back through the list.

11 Q I understand that. I understand that. That's

12 why I'm keeping the list. So --

13 A Some are higher for warnings, they're

14 appropriate warnings, and some are lower risks, things

15 that are something -- a precaution, and that would be

16 something that needs to be divided from Warnings and

17 Precautions.

18 Q All right. What is your 25th criticism of the

19 IFU?

20 A Let me go through. There's nothing about --

21 okay, Adverse Reactions, it should be -- Adverse

22 Reactions is what they're calling it; they want to call

23 it that, or complication. And let's look at that.

24 Q All right. Dr. Parisian, before you -- I'm

Page 153

1 still making my list. So what's your 26th criticism of

2 the IFU?

3 A Well, I'm looking at the Adverse Reaction

4 section.

5 Q Can you list the 26th criticism? Otherwise,

6 we'll move on.

7 A Yeah, sure I can.

8 Q Okay.

9 A I mean, looking at it right away, one of the

10 issues is the use of the word "transitory" or "local

11 irritation" -- "transitory local irritation." The

12 words --

13 Q And that's a criticism?

14 A Oh, it's a big criticism.

15 Q Okay. What's your next criticism?

16 A Well, no, why is it my criticism?

17 Q No, I'm sorry --

18 A It should be --

19 Q Dr. Parisian, listen to my question. Stick

20 with me, okay? What's your next -- what's your 27th

21 criticism of the IFU?

22 A Okay, but let's go back to 26.

23 Q No, I'm taking this deposition, Doctor.

24 MR. LUNDQUIST: Doctor, it's all right, if he

Page 154

1 doesn't --

2 BY MR. HUTCHINSON:

3 Q I'm going to ask you a question. What's your  
4 27th criticism of the IFU?

5 MR. LUNDQUIST: If he doesn't want the basis  
6 for it, he's welcome to ask what the criticisms are.

7 THE WITNESS: And that isn't what --

8 MR. LUNDQUIST: That's fine.

9 MR. HUTCHINSON: I'm totally entitled to know  
10 what her criticisms are.

11 MR. LUNDQUIST: You are.

12 BY MR. HUTCHINSON:

13 Q What's your 27th criticism?

14 A Well, my 27th is that instead of the word  
15 "transitory," it should be "permanent."

16 Q Okay, what's your -- do you have any other  
17 criticisms of the IFU?

18 A And it should be -- yes.

19 Q Okay. What's the next one?

20 A The Adverse Reactions is totally inadequate.  
21 There's nothing about need for revision surgery, and  
22 there's nothing about the difficulty removing of the  
23 mesh. There's nothing about the potential risk for  
24 infection, chronic pain, dyspareunia, change in your

Page 155

1 vagina in terms of scarring. None of that information  
2 is in here. So the Adverse Reaction is totally  
3 inadequate --

4 Q Okay.

5 A -- in terms of the information.

6 Q Do you have any other criticisms of the IFU?

7 A Let me --

8 Q And your 28th criticism was the Adverse  
9 Reactions language, correct?

10 A It's still inadequate.

11 Q I'm sorry, is that correct?

12 A Yes, it's totally inadequate.

13 Q Do you have any other criticism of the IFU?

14 MR. LUNDQUIST: Just for clarification, are  
15 you talking about just the inadequacy or what she thinks  
16 should be in here, or are you asking about --

17 MR. HUTCHINSON: I'm talking about her  
18 criticisms.

19 MR. LUNDQUIST: Fair.

20 THE WITNESS: Oh, because I'm trying to tell  
21 you what should be in there.

22 BY MR. HUTCHINSON:

23 Q Have we discussed all of your criticisms of  
24 the IFU?

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1 A Yeah, it's -- and I can summarize. It's --

2 MR. LUNDQUIST: You don't need to summarize,  
3 that's okay. Thank you. If you've gone through them,  
4 Dr. Parisian, I think --

5 THE WITNESS: So you're going to ask me what  
6 needs to be in it?

7 BY MR. HUTCHINSON:

8 Q No, I'm going to ask you to summarize for us  
9 what your criticisms are for the IFU.

10 A Okay. The design of the document is not  
11 correct. The information for the physician that he  
12 needs to know about choosing this device is not up  
13 front.

14 There's too much discussion of the device.  
15 You can put that later in the labeling, to describe the  
16 device.

17 The Instructions For Use, the surgical  
18 procedure needs to be later in there. They need to tie  
19 the precautions that go with the Instructions For Use  
20 with pictures. You need to have pictures, so that the  
21 physician would know what the potential procedure is.  
22 You can't have pictures not together.

23 Adverse Events is deficient. It doesn't talk  
24 about the permanent nature of the complications, in

Page 157

1 terms of risk versus benefit.

2 So the sum is that it's an inadequate label in  
3 terms of risk versus benefit information for a physician  
4 choosing to use this product versus another product.

5 It also doesn't talk about the post-marketing  
6 history, the learning curve, and what a physician needs  
7 to do to be able to use this device safely on a patient.

8 And what kind of information oftentimes the  
9 label will have information for consulting for your  
10 patients, counseling your patients, there's nothing in  
11 here for a physician about information you give to a  
12 patient.

13 Q What should the label say?

14 A Okay, the label should say that -- just what  
15 I said, in terms of the summary. It needs to put the  
16 risk information, the warnings and precautions divided  
17 separately up front, with the contraindications under  
18 the device description with the intended use, the  
19 indication for use.

20 It needs to convey if there are any patients  
21 that are not appropriate; what kind of training a  
22 physician has. The difficulty with tensioning needs to  
23 be in here, and in implanting. It also needs to, as  
24 post-market data is obtained, the high failure rate at

Page 158

1 12 weeks, in terms of this device: Do you want to use  
2 this product versus another product?

3 It also needs to have a list of the adverse  
4 events, complications that can occur, that they can be  
5 permanent, that it can be difficult to remove a mesh,  
6 that infections cannot be treated, perhaps; that removal  
7 of the mesh -- you cannot remove all of the mesh and you  
8 may still have infection.

9 It also doesn't discuss anything about nerve  
10 injury, that people will have chronic pain. It  
11 doesn't -- it implies that the issues of complications  
12 are going to be temporary and transient. Those are not  
13 the right words, and the company internally was talking  
14 that was the wrong term to use.

15 So, you know, it just doesn't convey the risk  
16 versus benefit information in an adequate prescription  
17 label for a 21 C.F.R. 801.109.

18 Q Have we discussed all the language you believe  
19 that should be in the IFU?

20 MR. LUNDQUIST: Object to form.

21 THE WITNESS: That's what I think.

22 BY MR. HUTCHINSON:

23 Q Dr. Parisian?

24 A I think that, in terms of, I am not a

Page 160

1 talked about all the language that you believe should be  
2 in the IFU?

3 A The -- yeah, I think also it needs to have an  
4 adverse reaction that failure has been found at 12  
5 weeks, in terms of the medical literature --

6 Q Okay, anything else?

7 A -- and their own data.

8 Q Anything else?

9 A That their long-term performance hasn't been  
10 determined by the company.

11 Q Anything else? Dr. Parisian, anything else?

12 A I'm thinking, I'm thinking. I think also, in  
13 terms of the fixation, the fixation, there's no  
14 information about the success of fixation with the  
15 Ethisorb.

16 Q I'm talking about the language.

17 A Right, no, the right --

18 Q So tell me, have we discussed everything?

19 A There's this whole discussion of the freeze in  
20 the design, but there's nothing about that this has  
21 never been used for this indication before, in terms of  
22 the Dura Patch that they're using.

23 Q Anything else?

24 A That information needs to be there to tell the

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1 clinician, and so as an FDA reviewer looking at the  
2 warnings and looking at what the medical literature has  
3 covered, those are my opinions.

4 We also have to take Dr. Miklos, because he  
5 actually can talk --

6 Q I'm not talking about Dr. Miklos.

7 MR. LUNDQUIST: She's answering your question.  
8 She's answering your question.

9 MR. HUTCHINSON: Move to strike as  
10 nonresponsive.

11 MR. LUNDQUIST: Doctor, you can continue your  
12 answer.

13 THE WITNESS: I'm going to refer to him in  
14 order to talk about the training, because he was a  
15 preceptor and he would know about the adequacy for the  
16 IFU training, because I haven't focused on that.

17 BY MR. HUTCHINSON:

18 Q Okay, and have we talked about all of your  
19 opinions regarding language that should be in the IFU?

20 A All the -- all the language? Because -- did  
21 we talk about the language? I mean, we talked about it  
22 in the beginning, the dyspareunia, product -- is that in  
23 your...?

24 Q I'm asking you. I'm asking you, have we

Page 161

1 physician that the fixation hasn't been determined, and  
2 there's no long-term data about that. So difficulty  
3 removing, training. What else? I think that's about  
4 it.

5 Q Dr. Parisian, are you aware of any IFU on the  
6 market that has everything that you have suggested in  
7 it, and in the order in which you've suggested it?

8 A Actually, a lot of the information was  
9 suggested by the FDA in 2008 --

10 Q Move to strike as nonresponsive. I'm not  
11 asking about the FDA.

12 A Well, there's different components of it.

13 Q My question -- my question to you is, are you  
14 aware of any IFU on the market that has all the  
15 information in it and in the order you think it should  
16 be in it, yes or no?

17 A I don't know. I mean, I don't think so,  
18 because this is specifically looking at the documents  
19 for TVT Secur. The documents for TVT-O and the  
20 documents for TVT and other product would be different,  
21 but in terms of the information, there's -- some other  
22 of the labels may actually have some of that.

23 Q Dr. Parisian, did Ethicon do anything correct  
24 when they drafted this IFU for TVT Secur, anything that



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1 they did well?

2 A Let me look. In terms of this IFU, no.

3 Q Okay, and Dr. Parisian, you'll know that the  
4 FDA did review this IFU before it cleared TVT Secur,  
5 correct?

6 A It was included in the 510(k) package, but the  
7 FDA reviewed it for the intended use. They didn't  
8 review it, they don't approve it.

9 Q Well, my question to you is: You do know that  
10 the FDA looked at the IFU that we've talked about before  
11 it cleared TVT Secur, correct?

12 MR. LUNDQUIST: Objection.

13 THE WITNESS: No, we know that it was in the  
14 FDA's submission, the 510(k). I will agree with that.  
15 BY MR. HUTCHINSON:

16 Q Okay.

17 A We don't really have any comments. We have  
18 Dr. Herrera saying he doesn't know how you could put  
19 this device in. So FDA didn't approve that. That's an  
20 IFU.

21 Q I'm not talking about approving, I'm talking  
22 about clearing.

23 A Well, you're --

24 Q FDA -- just stick with me. FDA cleared TVT

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1 Q Did FDA -- strike that. Did Ethicon violate  
2 any federal regulations with the IFU that was marked as  
3 Exhibit 6?

4 A Yes, 21 U.S.C. 352(a) --

5 Q Any others?

6 A Well, I'm explaining it. I'm answering your  
7 question.

8 MR. LUNDQUIST: Let her finish.

9 THE WITNESS: 21 U.S.C. 352(a)(f)(1), (f)(2),  
10 in terms of mis-branding; 21 C.F.R. 801.109, adequate  
11 prescription label; 21 C.F.R. 1.21, failure to reveal  
12 material facts. Twenty-one -- those would be the main  
13 ones in terms of the labeling, adequate instructions for  
14 use. Yes, sir.

15 BY MR. HUTCHINSON:

16 Q And this --

17 A So those are violated. Those are not  
18 consistent with the information that -- and I'm not  
19 going to say violated. Those are not in compliance. If  
20 I was an FDA regulatory expert, with the requirements  
21 for an adequate label, based on information that the  
22 company has, especially in 2010, because we're looking  
23 at labels that began when it was first cleared, but once  
24 it was marketed, and by 2010, that label is not an

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1 Secur, correct?

2 A They did, but not that label.

3 Q And FDA had this label at their office when  
4 they cleared TVT Secur, correct?

5 A It was with the 510(k) --

6 Q Is that correct?

7 A Yes, it was with the 510(k) submission --

8 Q And that clearing --

9 A -- and Herrera's comment is that --

10 Q And that clearing -- just a minute. By  
11 clearing the TVT Secur, FDA gave Ethicon the green light  
12 to market this, correct?

13 A Only to market it, but not with that IFU.

14 Q Right, and --

15 A FDA doesn't review the IFU. That's up to  
16 Ethicon, and the only thing the FDA reviewed in the  
17 510(k) was the intended use, and the submission and the  
18 representation that this device was exactly the same as  
19 TVT and TVT-O, and some of that information is from TVT  
20 and TVT-O.

21 And so the FDA only reviews labeling for the  
22 intended use. They didn't -- that's not cleared by the  
23 FDA or approved by the FDA, and you can say it all you  
24 want, but it's not.

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1 adequate label for Ms. Garcia.

2 Q Let's look at Exhibit number 7. That's the  
3 patient brochure that you have in front of you, correct?

4 MR. LUNDQUIST: You're going to launch into a  
5 whole new -- as far as the brochure, so is now a good --

6 MR. HUTCHINSON: Patient brochure?

7 MR. LUNDQUIST: Yeah, I figure you probably  
8 have a good deal of questions on that. Can we kind of  
9 take a --

10 MR. HUTCHINSON: I really don't think I'm  
11 going to do --

12 MR. LUNDQUIST: Maybe a 30-minute lunch break,  
13 unless you just want to --

14 MR. HUTCHINSON: Why don't we -- so you want  
15 to take a break now?

16 MR. LUNDQUIST: I mean, we've been going for  
17 about three and half hours. So just 30 minutes, back  
18 at, let's call it, back 10 to one?

19 BY MR. HUTCHINSON:

20 Q Well, let me ask you this: Do you have a lot  
21 of opinions about the patient brochure that we haven't  
22 already talked about?

23 A Yeah.

24 MR. HUTCHINSON: Let me -- all right, why

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1 don't we take a -- plaintiff's counsel, you want to take  
 2 a --  
 3 MR. LUNDQUIST: Thirty.  
 4 MR. HUTCHINSON: -- 30-minute lunch, is that  
 5 right?  
 6 MR. LUNDQUIST: Let's call it that.  
 7 MR. HUTCHINSON: Okay. All right, fair  
 8 enough.  
 9 (Luncheon recess taken from 12:24 p.m. to 1:10 p.m.)  
 10 BY MR. HUTCHINSON:  
 11 Q We ready?  
 12 A Yes.  
 13 Q Okay. We're back on the record after having  
 14 lunch and ready to go. Dr. Parisian --  
 15 A Yes.  
 16 Q -- the label in this case is the IFU, correct?  
 17 A Yes, well -- the label, yes, as opposed to  
 18 labeling.  
 19 Q Correct, but we're talking -- when we talk  
 20 about the label, you and I are talking about the same  
 21 thing in this case?  
 22 A In this case, yes.  
 23 Q And I think, before we took a break, you gave  
 24 us 28 to 30 reasons or so about why you believe the IFU

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1 correct?  
 2 A It's misbranded. I mean, I've had a lot of  
 3 other opinions about defective design, but we're talking  
 4 about the IFU, and the label is misbranded, it's  
 5 inadequate, particularly by the time Ms. Garcia has her  
 6 surgery.  
 7 Q Does that mean that the product was  
 8 defectively designed?  
 9 A Just based on the labeling? In terms of the  
 10 training for the physician, yeah, we discussed that in  
 11 terms of the design in the very beginning.  
 12 Q Okay. Did you determine -- did you do any  
 13 tests to determine if the product was defectively  
 14 designed?  
 15 A Yeah, I think I have -- well, I haven't done  
 16 any physical tests.  
 17 Q Okay.  
 18 A I've looked at documents about it, and --  
 19 Q Okay.  
 20 A -- and reports.  
 21 Q Are you relying on -- I know you've looked at  
 22 documents, but are you relying on any peer-reviewed  
 23 publications or scientific literature as the basis of  
 24 your opinion that the product is defectively designed?

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1 was defectively designed, correct?  
 2 MR. LUNDQUIST: Object.  
 3 THE WITNESS: And then I summarized, tried to  
 4 say why, because it's not the points as much as the way  
 5 it's laid out.  
 6 BY MR. HUTCHINSON:  
 7 Q And the label is part of the product?  
 8 A Yes.  
 9 Q And you can't separate product from the label;  
 10 meaning the two of them go hand-to-hand, right?  
 11 A Well, in what sense? In terms of a regulatory  
 12 sense, you can. If you're talking about a 510(k)  
 13 clearance, they're different. Because the only thing  
 14 that's really reviewed is the indications for use in  
 15 terms of 510(k) clearance, and then you get a nice  
 16 clearance letter saying it's up to you, manufacturer, to  
 17 ensure your labeling, which would be your IFU, is  
 18 adequate.  
 19 Q Well, certainly Ethicon couldn't sell the TVT  
 20 Secur device without an IFU, could they?  
 21 A No, they have to indicate what the intended  
 22 use is.  
 23 Q So if the label is defectively designed, it's  
 24 your opinion that the product's defectively designed,

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1 A I would look at the Cochran report. The  
 2 Cochran report went and came up looking at all  
 3 randomized controlled studies that had been done and  
 4 said, very nicely, that it was not an adequate product  
 5 to use and that it would have been withdrawn from the  
 6 market.  
 7 Q Can your theory the TVT Secur product is  
 8 defectively designed, can that theory be tested?  
 9 A From a regulatory point of view? Sure. In  
 10 terms of the methodology that I'd use is exactly the  
 11 same methodology I would have used at the FDA to make  
 12 that same determination: Is this an adequate device?  
 13 Are the instructions adequate?  
 14 So that that methodology can be tested, and  
 15 then the post-marketing reports actually substantiates  
 16 that it wasn't adequately designed --  
 17 Q Have you done --  
 18 A -- in their own internal discussions. So  
 19 based on the medical literature, their own company  
 20 reports, their own testimony, their own documents,  
 21 and -- it is inadequately designed. It did not meet --  
 22 by "inadequately designed," I mean it's not meeting its  
 23 users' needs, in terms of what the design requirements  
 24 are, and that would be under 21 C.F.R. 820.

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1 Q Has your theory been tested?

2 A Has my theory...? You mean my process or

3 methodology?

4 Q No, I'm talking about your opinion that the

5 TVT Secur device is defectively designed. Has that

6 theory been tested, yes or no?

7 A I don't understand the question.

8 Q Have you done any tests to determine if the

9 TVT Secur device is defectively designed?

10 A No, I have not.

11 Q Are you aware --

12 A Can I clarify? You mean physical tests? Have

13 I taken it into a laboratory and done physical tests?

14 No.

15 Q Well, have you done any types of tests to

16 determine if the product is defectively designed?

17 A Other than looking at the internal documents

18 and company reports and the post-marketing, I mean, it's

19 the company documents that have actually been what's

20 defectively designed and as my basis for that opinion,

21 and the medical literature.

22 Q Is that a no?

23 A I don't think I'm understanding your question.

24 Q Okay. Have you done any test to determine if

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1 assessment.

2 BY MR. HUTCHINSON:

3 Q Has a safer design been manufactured?

4 A Well, in terms of Ms. Garcia --

5 MR. LUNDQUIST: Form.

6 THE WITNESS: -- we have the TVT-O. Since Dr.

7 Walss has been familiar with that, he said that's what

8 he would have used if he had known about the potential

9 risks.

10 BY MR. HUTCHINSON:

11 Q Well, my question to you is: Do you believe

12 that a safer design, other than a safer design than

13 TVT -- strike that.

14 Do you believe that there is a safer design on

15 the market compared to TVT Secur?

16 MR. LUNDQUIST: Form.

17 THE WITNESS: Yes.

18 BY MR. HUTCHINSON:

19 Q And what was that? What was that safer

20 design?

21 A Based on the company documents, the medical

22 literature, Dr. Miklos, it would be the TVT and the

23 TVT-O. Now, I'm not saying they're safe, but I'm saying

24 they're safer than the TVT Secur.

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1 the TVT Secur device is defectively designed?

2 MR. LUNDQUIST: Object.

3 THE WITNESS: Where I put it in the laboratory

4 and tested it? I haven't done any testing like that.

5 BY MR. HUTCHINSON:

6 Q I'm talking about any tests.

7 MR. LUNDQUIST: Object to form.

8 THE WITNESS: I've done what a regulatory

9 expert would do in terms of looking at adequacy of

10 design and what I would have done at FDA. I used the

11 same kind of documents.

12 BY MR. HUTCHINSON:

13 Q But have you done any tests other than

14 physical tests?

15 MR. LUNDQUIST: Object to form.

16 THE WITNESS: I haven't done any physical

17 tests, but I've used the documents that a regulatory

18 expert would rely on to come up with that opinion.

19 I'm not -- I don't -- are you trying to say,

20 am I an engineer that would have done physical

21 laboratory testing? No, I'm not, but the documents I've

22 used are the same documents that I would have used at

23 the FDA to say, is there an issue with this device;

24 health risk assessment, in terms of a health risk

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1 Q Are you relying on any controlled study to

2 support your opinion that the TVT Secur caused injury to

3 Ms. Garcia?

4 A A controlled study? Why would I rely on a

5 controlled study? I'm relying on all the company

6 documents and the information about the potential risks.

7 Q And that's all?

8 A And also we have Dr. Miklos, Dr. Walss, you

9 know, those -- in terms of a health risk assessment, I'm

10 relying on the totality of all those documents.

11 Q Right, but I'm asking you about a controlled

12 study. Are you relying any controlled study, yes or no?

13 A Not one specific controlled study, no, sir.

14 Q What -- and I believe it's your testimony that

15 the TVT or TVT-O, in your opinion, would be the proposed

16 alternative safer design, is that right?

17 A Based on what Dr. Walss said, I would go with

18 the TVT-O.

19 Q Okay.

20 A Or no treatment at all.

21 Q And are you aware of any study comparing the

22 current IFU that we have talked about as Exhibit 6 to

23 the proposed IFU that you claim is safer?

24 A The current study -- I know we have

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1 Dr. Miklos, it's not -- from his clinical practice as a  
2 physician and knowledgeable at the --

3 Q I'm not asking about Dr. Miklos, I'm asking  
4 about studies.

5 A Well, there hasn't been a study of my proposed  
6 label tested because it's based on documents that I've  
7 reviewed. If the company wanted to do that, they could  
8 do that, but I haven't seen that the company has done  
9 such a study.

10 Q The IFU that you propose has never been  
11 cleared by the FDA, has it?

12 A It wouldn't need to be. The company could  
13 have done it immediately.

14 Q Is that a no?

15 A That's correct, and by 2010, which is the time  
16 period we're talking about, the company had not updated  
17 their label. So they would have the IFU that we  
18 discussed, and I don't know that -- and FDA doesn't have  
19 to clear a 510(k)'s label. The manufacturer can update  
20 it immediately.

21 Q In fact, the IFU that you propose has never  
22 been submitted to the FDA, has it?

23 A That's correct.

24 Q Okay, not even by you.

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1 BY MR. HUTCHINSON:

2 Q Exactly. Am I correct?

3 A In terms of -- I --

4 MR. LUNDQUIST: Form.

5 THE WITNESS: That's correct, I mean, because  
6 nobody would have written the entire label -- I didn't  
7 write a label. I told you what was deficient in your  
8 label and what should be there. So there isn't a label  
9 that I've even created, other than to tell you what my  
10 opinions are in terms of what's missing from the label.

11 BY MR. HUTCHINSON:

12 Q Is -- so I guess it's fair to say that no one  
13 in the world has ever marketed a product with an IFU --  
14 with the IFU like the one you believe is safe, correct?

15 MR. LUNDQUIST: Object to form.

16 THE WITNESS: Well, the label --

17 BY MR. HUTCHINSON:

18 Q I'm just asking for a yes or no. Then you can  
19 explain your answer.

20 MR. LUNDQUIST: Form.

21 THE WITNESS: Yes, because we're talking about  
22 a TVT Secur label, not every label in every one in the  
23 world, and the company could have used that label at any  
24 time, and making a label that's very specific for their

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1 A Why would it be, by me? That's correct.

2 Q And it's fair to say that no mesh manufacturer  
3 has ever included an IFU like the one you believe is  
4 safe, with their product?

5 MR. LUNDQUIST: Form.

6 THE WITNESS: I've seen various mesh  
7 manufacturers' labels. They have components of the  
8 information that I have, at various different times.  
9 Their labels have been changing since the FDA's public  
10 Health Announcement 2008. So their labels are evolving.

11 So much of that information isn't included in  
12 the labels. I think there's a discussion in 2009, when  
13 the company's comparing TVT's label using the word  
14 "transitory" versus AMS label, where the transitory  
15 doesn't occur. So there are components of those  
16 statements --

17 BY MR. HUTCHINSON:

18 Q I'm not talking about components, I'm talking  
19 about an IFU exactly like the one that you had proposed  
20 to be safer.

21 MR. LUNDQUIST: Object to form.

22 THE WITNESS: "Exactly" is the word, yes,  
23 but --

24 // //

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1 post-marketing information, which had never been  
2 included in their initial label. They had one label  
3 that came out and was never updated with any post-market  
4 safety information.

5 BY MR. HUTCHINSON:

6 Q Is there a mesh manufacturer of a mini-sling  
7 on the market that has an IFU that you believe is better  
8 than Ethicon's?

9 A There are labels for other manufacturers that  
10 have been updated over time that are better than you  
11 would compare to the 2011 label -- what date was that  
12 label that you showed me? Oh, that was the very first  
13 label.

14 Yeah, the other manufacturers that I've seen  
15 labels that are better than TVT's label, one would be  
16 AMS, one would be Boston Scientific. Their labels have  
17 different components, they're not perfect labels, but  
18 they're more robust than the Ethicon label.

19 Q Let's talk about the IFU that you propose and  
20 compare it to the current IFU for TVT Secur, okay?

21 A Well, you asked me my opinions on the --  
22 I didn't propose and draft a label.

23 Q Okay, and in fact, that's something that  
24 you're not doing in this case, correct?

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1 A I wasn't asked to do that. You asked me  
2 specifically what are my opinions on the label, and  
3 I gave you my opinions on the label. I didn't draft a  
4 better label, other than to tell you how I would  
5 rearrange the information. So there isn't a drafted  
6 label by me other than the opinions.

7 Q Okay, and so that's something you've not done  
8 is, you've not drafted a better label than the one for  
9 TVT Secur, correct?

10 A I haven't physically drafted -- that's what  
11 I wanted to be clear. I haven't physically drafted a  
12 label. I've told you what's deficient in terms of  
13 inadequate information. There are consultants like me  
14 that could draft a label, but I haven't done that.

15 Q Since you haven't talked with Dr. Walss, then  
16 you don't know if the IFU that you proposed would have  
17 made any difference in how he selected the product, do  
18 you?

19 MR. LUNDQUIST: Object to form.

20 THE WITNESS: Based on his deposition, I do.

21 BY MR. HUTCHINSON:

22 Q Okay.

23 A His deposition said it did. He repeatedly  
24 said if he had known that, he wouldn't have -- what was

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1 Q My question is: Since you haven't spoken with  
2 Dr. Walss, do you know if the IFU that you proposed  
3 would have any made difference in the way he discussed  
4 the procedure with Ms. Garcia?

5 MR. LUNDQUIST: Object to form.

6 THE WITNESS: I only can rely on his  
7 testimony, and he said it would have.

8 BY MR. HUTCHINSON:

9 Q So it's your opinion that a TVT-O would be a  
10 safer design?

11 A It's relative. It's safer than a TVT Secur.

12 Q And TVT-O is a multi-sling -- multi-incision  
13 sling, correct?

14 A Right.

15 Q And a TVT Secur is a one-incision sling.

16 A Single-incision, yes.

17 Q So it's your opinion that a two-incision sling  
18 is better than a one-incision sling?

19 A No, it's not my opinion. My opinion is that  
20 for a physician to know how to be able to use a device,  
21 it makes it a better device. Dr. Walss is familiar with  
22 a TVT-O, and he was not familiar and was not able to be  
23 familiar with the tensioning issues because the company  
24 didn't instruct him on it for the TVT-S. So you're

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1 in the IFU, he wouldn't have used the product, he would  
2 have used the TVT-O, which he knew how to use and had  
3 used. So he repeatedly said that.

4 Do you want examples or just, is that enough  
5 for you?

6 Q Since you haven't spoken with Dr. Walss, do  
7 you have any idea if the IFU that you propose would have  
8 made any difference in the way he performed a  
9 risk/benefit analysis?

10 A Based on his testimony, the information that  
11 I was adding would have, according to him, have changed  
12 his use of the product. I haven't physically spoken to  
13 him, but knowing what he said was important to him in  
14 terms of the information and use of the product, yes,  
15 I think it would have, but that would be up to him to  
16 answer that.

17 Q And do you know if the IFU that you proposed  
18 would have made any difference in the way he discussed  
19 the procedure with Ms. Garcia?

20 A The way I did propose it, yes, because I was  
21 adding post-market information, which he didn't have,  
22 and it could have been sent to him in a Dear Doctor  
23 letter, it could have been told him by the sales rep.  
24 So there's other communications besides the IFU.

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1 always better off having a doctor using a product that  
2 he's aware how to use rather than one he's not.

3 Q Dr. Parisian, you've never designed an  
4 alternative design, like the one you believe is safer,  
5 have you?

6 A For what?

7 Q For stress urinary incontinence.

8 A An alternative design of what?

9 Q An alternative design of the TVT Secur.

10 A Oh, so you're saying for another device.

11 Q Yes.

12 A No, I've not designed a device, but Dr. Walss,  
13 which is the important part, said he would have used the  
14 TVT-O, which has, based on the company's documents, a  
15 lower risk of recurrence of SUI and other problems. It  
16 has risks, but lower risks than TVT Secur.

17 Q I want to hand you what we'll mark as  
18 Exhibit 8 to your deposition.

19 A Sure.

20 (Whereupon, Exhibit 8 was marked for  
21 identification.)

22 BY MR. HUTCHINSON:

23 Q I believe you've seen this document before,  
24 correct?

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1 A Yes, General Controls of Medical Devices.  
 2 Q In fact, this is on the reliance list.  
 3 A Yes, sir.  
 4 Q And when you worked with FDA, you knew what  
 5 general controls for medical devices were, didn't you?  
 6 A Sure.  
 7 Q General Controls provide the FDA with means of  
 8 regulating devices to ensure safety and effectiveness,  
 9 correct? I'm in the introduction part.  
 10 A Where are you reading?  
 11 Q The introduction part.  
 12 A General Controls...  
 13 Q General Controls provide the FDA with means of  
 14 regulating devices to ensure safety and effectiveness?  
 15 A Right, Congress required that the FDA would  
 16 come out with General Manufacturing Practices, GMP.  
 17 Q And you agree with that statement I just read,  
 18 correct?  
 19 A That was the purpose of the --  
 20 Q I understand.  
 21 A Yes.  
 22 Q I'm not asking about the purpose. Just stick  
 23 me, and we'll get through this.  
 24 A Yes.

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1 Q You agree with that, and the next sentence  
 2 says, "General Controls and the amendments apply to all  
 3 medical devices." You agree with that correct?  
 4 A Yes, sir.  
 5 Q And including Ethicon's?  
 6 A All devices, all --  
 7 Q Including the TVT Secur that Ms. Garcia  
 8 received, correct?  
 9 A Yes.  
 10 Q Those standards apply to Ethicon and the  
 11 product, correct?  
 12 A All medical devices sold in the United States,  
 13 yes.  
 14 Q I'm sorry, is that correct?  
 15 A Yes. I think I have two. Did somebody else  
 16 need one?  
 17 Q If you look -- if you turn with me to  
 18 page 2 --  
 19 A Um-hum.  
 20 Q -- under Key Points, it says,  
 21 "General Controls are the basic  
 22 authorities of the Medical Device Amendments  
 23 that provide FDA with the means of regulating  
 24 devices to ensure safety and effectiveness."

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1 You agree with that, right?  
 2 A Yes.  
 3 Q And the FDA's General Controls, they address  
 4 safety now, right?  
 5 MR. LUNDQUIST: Object to form.  
 6 THE WITNESS: Well, the purpose is to attempt  
 7 to address safety. They -- the FDA doesn't specify  
 8 General Controls per se for each manufacturer.  
 9 BY MR. HUTCHINSON:  
 10 Q But these standards address safety, correct?  
 11 A Right, under good manufacturing practices.  
 12 Q And these controls, or standards, are  
 13 mandatory for Ethicon to follow, correct?  
 14 A Yes.  
 15 (Whereupon, Exhibit 9 was marked for  
 16 identification.)  
 17 BY MR. HUTCHINSON:  
 18 Q Okay, and if you look at what I'll hand you as  
 19 Exhibit 8 -- I'm sorry -- Exhibit 9 to your deposition,  
 20 Dr. Parisian?  
 21 A Um-hum, yes, sir. This the newest one.  
 22 Q Guidance for Industry and Food and Drug  
 23 Administration Staff, correct?  
 24 A Well, this is the newest one. There's been a

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1 series of them before that. This is the 2014 --  
 2 Q But we'd want to look at the newest one,  
 3 wouldn't we?  
 4 MR. LUNDQUIST: Form.  
 5 THE WITNESS: Depends what your question is.  
 6 Because we're talking about back in -- I have no --  
 7 I have no need to quibble about this. I'm just saying,  
 8 this is the newest one.  
 9 BY MR. HUTCHINSON:  
 10 Q Well, let's look at Exhibit 9. You relied on  
 11 this for reaching your opinions, correct?  
 12 A Yes, sir.  
 13 Q And when you worked at FDA, you relied on  
 14 guidance documents like this to educate you on certain  
 15 topics?  
 16 A Oh, I didn't rely on this, I already knew  
 17 this. I had been trained, everything in here. This is  
 18 basically for manufacturers to try to facilitate their  
 19 awareness of when they need to put in a 510(k). So  
 20 there's -- there was no change in the regulations.  
 21 Q Well, so here, if we look at this document, we  
 22 have FDA giving guidance to both industry and its staff  
 23 about the 510(k) process, right?  
 24 A Yes, new staff, basically, but the regulations



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1 hadn't been changed.

2 Q Do you disagree with anything the FDA was

3 telling the medical community and its own staff in this

4 document?

5 A No, I'm not. I'm just saying I knew about

6 this long before this guidance.

7 So do you have a question?

8 Q Let's turn to page 3.

9 A Okay. Got it.

10 Q It's the last sentence. It says,

11 "Because...", the last sentence on page 3. Do you see

12 that?

13 A Yes, sir.

14 Q Okay. It says,

15 "Because devices are classified according

16 to the level of regulatory control necessary

17 to provide a reasonable assurance of safety

18 and effectiveness, classification of a new

19 device through the 510(k) process requires FDA

20 to determine the issues of safety and

21 effectiveness presented by the new device and

22 the regulatory controls necessary to address

23 those."

24 Did I read that correctly?

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1 A Yes, sir.

2 Q And did FDA get it wrong here, or is it

3 correct?

4 A No, it's right.

5 Q So basically you're saying, or -- basically,

6 what you would agree with, as we kind of sum it up, is

7 the 510(k) review provides reasonable assurance of

8 safety and effectiveness.

9 MR. LUNDQUIST: Object to form.

10 THE WITNESS: No, no, the term "reasonable" is

11 used with PMA. It determines the issues of safety and

12 effectiveness, based on the predicate device. The

13 predicate device, unlike a PMA, is used for clearance of

14 the -- supportive clearance of the 510(k) for the device

15 substantially equivalent. So yeah, that's correct.

16 BY MR. HUTCHINSON:

17 Q Okay.

18 A And if you're found substantially equivalent

19 to a predicate device, that controls.

20 Q I know that. We'll get to that in a minute,

21 but if the device has been 510(k) cleared, the FDA has

22 found reasonable assurance of safety and effectiveness,

23 fair enough?

24 MR. LUNDQUIST: Form.

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1 THE WITNESS: No, you're adding -- where do

2 you see "reasonable"?

3 BY MR. HUTCHINSON:

4 Q On page 3.

5 A Page 3, okay. Reasonably assured of safety --

6 to provide, okay, but that's not "reasonable," because

7 they use "reasonable" in the PMA regs, and --

8 Q Just, if you could stay with me. If a device

9 has been cleared in the 510(k) process, you'll agree

10 that FDA has found there's a reasonable assurance of

11 safety and effectiveness, correct?

12 MR. LUNDQUIST: Object form.

13 THE WITNESS: Yes, based on the predicate.

14 BY MR. HUTCHINSON:

15 Q Thank you, and the 510(k), that relates to

16 clearance of the device, not approval.

17 A That's right.

18 Q And that's something that would be relevant in

19 this case if we wanted to have a full picture of the

20 regulatory background of TVT Secur.

21 MR. LUNDQUIST: Object to form.

22 THE WITNESS: Of course it's relevant.

23 BY MR. HUTCHINSON:

24 Q Okay. It would also explain the history, the

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1 regulatory history of the product, wouldn't it?

2 A Yes. Do you want to discuss that?

3 Q We will in a minute.

4 A Okay. I want to understand the question,

5 here.

6 Q If you'll turn -- well, let's switch gears for

7 a minute, and let's talk about -- well, while we're on

8 here, while we're talking about FDA 510(k) clearance,

9 the 510(k) also relates to the safety of the device,

10 correct?

11 MR. LUNDQUIST: Form.

12 THE WITNESS: Based on the predicate device,

13 but only to -- the device has not been marketed, so

14 based on the safety of the prior device.

15 BY MR. HUTCHINSON:

16 Q If we have a -- strike that. Let's talk about

17 Prolene sutures for a minute. You're familiar with

18 Prolene suture, I believe you've already testified to,

19 correct?

20 A Yes, sir.

21 Q And I'll hand you what we'll mark as

22 Exhibit 10 to your deposition.

23 (Discussion off the record.)

24 // //

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1 (Whereupon, Exhibit 10 was marked for  
 2 identification.)  
 3 MR. HUTCHINSON: Will? Pay attention. Make  
 4 sure that's on the record.  
 5 THE WITNESS: All right.  
 6 BY MR. HUTCHINSON:  
 7 Q Now, you've seen this document before, haven't  
 8 you?  
 9 A Yes, sir.  
 10 Q And you will agree that TVT Secur's mesh is  
 11 made of these knitted filaments that we talked earlier  
 12 about, of Prolene suture, right?  
 13 A Well, it's the same polypropylene.  
 14 Q It's the Prolene suture. It's knitted  
 15 filaments together.  
 16 A Right.  
 17 Q And if you look at this document, this is --  
 18 it says NDA 16-374, is that right?  
 19 A Yes, sir.  
 20 Q And that's the number that was assigned to the  
 21 NDA for Prolene sutures.  
 22 A Yes.  
 23 Q And FDA approved the NDA for Prolene sutures  
 24 on April 16, 1969, correct?

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1 A Yes, sir.  
 2 Q And it's been in use since.  
 3 A Yes, sir.  
 4 Q And these were approved by FDA as a drug.  
 5 A Under the drug regulations, because the  
 6 medical device regulations hadn't been made yet.  
 7 Q And that approval includes labeling, correct?  
 8 A Yes, that would include the labeling.  
 9 Q Right, so the FDA concluded that the Prolene  
 10 sutures were safe and effective for intended use.  
 11 A As a suture, yes, sir.  
 12 Q And FDA approval of NDA means there's a  
 13 finding by the FDA that that drug is safe and effective  
 14 for use in the human body, as labeled?  
 15 MR. LUNDQUIST: Object to form.  
 16 THE WITNESS: Yes, it was an NDA approved  
 17 product.  
 18 BY MR. HUTCHINSON:  
 19 Q And if somebody wanted a complete history  
 20 about -- a complete picture about the regulatory  
 21 history, this would be the starting point, won't it?  
 22 A This is where I started, yes, sir.  
 23 Q Okay, and over the years, there has been --  
 24 there have been supplements to NDA 16-374, correct?

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1 A Right, until it was transitioned over to CDRH.  
 2 Q And do you know how many supplements there  
 3 have been?  
 4 A No.  
 5 Q And one --  
 6 A I don't recall how many supplements there have  
 7 been.  
 8 Q Did you look?  
 9 A At one time I did.  
 10 Q You don't know now?  
 11 A I don't know, sitting here today.  
 12 Q And every time the FDA approves a supplement,  
 13 that's confirmation that Prolene suture is safe and  
 14 effective as labeled, correct?  
 15 MR. LUNDQUIST: Object to form.  
 16 THE WITNESS: For that specific indication.  
 17 They don't go back and re-look at everything. It's only  
 18 on a specific indication.  
 19 BY MR. HUTCHINSON:  
 20 Q Now, let's talk about before 1976. FDA  
 21 regulated medical devices just like they did drugs.  
 22 A No.  
 23 Q Before 1976?  
 24 A No. Let me explain.

Page 193

1 Q Okay.  
 2 A They had certain drugs -- certain devices that  
 3 the FDA was concerned about safety issues, and so the  
 4 FDA chose to apply the drug regulations to certain  
 5 devices that would be referred to as the "transitional"  
 6 devices.  
 7 So they were actually required to have an NDA  
 8 approval, and the requirements were comparable to what  
 9 was required at that time for approval, because those  
 10 have been evolving, too, in terms -- this was pre the  
 11 70's, when FDA would have required clinical trials.  
 12 Q Right.  
 13 A They didn't do that here, but --  
 14 Q Right. Well, but one of the medical devices  
 15 that FDA regulated just like drugs was the Prolene  
 16 sutures, correct?  
 17 A Yes, sir.  
 18 Q And --  
 19 A Just as a suture, not as a mesh.  
 20 Q And if we look at -- let me make sure  
 21 I understand something.  
 22 A Sure.  
 23 Q A pre-amendment device is one that was sold  
 24 before the Medical Device Act of 1976, correct?

Page 194

1 A For a medical device, yes, sir.

2 Q Okay.

3 A So we call it pre-amendment, but not all

4 pre-amendment devices were regulated as drugs. This was

5 a transitional pre-amendment device that actually the

6 NDA came over as a PMA approval when they got regulated,

7 devices.

8 Q And you'll agree that pre-amendment devices,

9 with a few very specific exceptions, were grandfathered

10 as safe and effective, correct?

11 A Yes.

12 Q Okay. In fact, that's what you wrote in your

13 book, "FDA Inside and Out."

14 A That's right, but that's not specifically --

15 you need to look at the section on transitional devices,

16 because this was already NDA-approved. So it is safe

17 and effective as a Prolene suture. It was transitioned

18 to having a PMA approval when it moved over to CDRH.

19 So it's a little higher standard than what

20 you're reading there for the pre-amendment device,

21 because not all of them have any kind of clinical

22 trials.

23 Q Right, but the Prolene sutures, that was a

24 pre-amendment device.

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1 A It was a transitional device, technically, but

2 it was pre-amendment.

3 Q And the Prolene mesh was a pre-amendment

4 device, correct?

5 A The surgical mesh was a pre-amendment device,

6 but it came if from Usher, I think, before 1976. So

7 mesh was pre-amendment. Prolene was NDA-approved. So

8 the material, the resin, was NDA-approved.

9 Q Well, Prolene mesh was grandfathered in as

10 safe and effective.

11 A Based on that it was a surgical mesh which was

12 pre-amendment. So the mesh -- yes, we're not -- I mean,

13 it's a cleared device. I'm not talking...

14 Q Right.

15 A But technically, surgical mesh was a

16 pre-amendment device. Prolene was an approved material

17 as an NDA.

18 Q And FDA has never done anything to change the

19 fact that Prolene mesh was grandfathered in as safe and

20 effective, have they?

21 A No.

22 Q Okay.

23 A It's based on the history. I don't think FDA

24 really could do anything.

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1 Q After 1976 amendments, Prolene sutures became

2 a PMA Class III device, right?

3 A Well, they're --

4 Q I'm sorry, is that right?

5 A Yes, they're a PMA-approved device, so

6 therefore, they're a Class III, but then they were

7 reclassified into 510(k) Class II.

8 Q And Class III devices require FDA review and

9 approval.

10 A Yes.

11 Q Okay, and in fact, Prolene sutures remained a

12 Class III device until the FDA down-classified it in

13 1990.

14 A Right. In fact, Ethicon wanted to keep it a

15 Class III device. It was the rest of the industry which

16 supported re-classification, and so FDA re-classified

17 it.

18 Q And what does it mean when something is

19 down-classified?

20 A It means that FDA -- in this particular case,

21 they said that they reviewed the medical literature and

22 they felt that there could be accurate, er -- adequate

23 controls to ensure safety and efficacy with using

24 general controls and special controls, rather than the

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1 controls -- also special controls, of the -- that have

2 to be developed in a PMA or NDA, so it could then, from

3 then on, be cleared as a 510(k).

4 Q All right. Let's talk about, going back to

5 Prolene mesh, though, that's a pre-1976 device?

6 A No, mesh, mesh in general. Surgical mesh was

7 used in the Vietnam War and it was pre -- pre-amendment.

8 Q I'm talking about Prolene mesh, pre-1976

9 device, correct? We just talked about that.

10 A Prolene is, yes, but it's based on a product,

11 the Prolene that actually had been NDA-approved.

12 Q And it's made of the knitted filaments, just

13 like the Prolene suture.

14 A Well, no, it doesn't look like suture. That's

15 where --

16 Q Okay, I'm not asking what it looked like. I'm

17 asking about what it's made of.

18 A Yes, it's made of the same resin.

19 Q Correct, and it's made of the exact material

20 previously approved by FDA as safe and effective,

21 correct?

22 A The resin is, which is used for the suture.

23 Q And because it was a pre-1976 device, it was

24 grandfathered in as safe and effective, as a Prolene

Page 198

1 mesh.

2 MR. LUNDQUIST: Object.

3 THE WITNESS: All surgical meshes were. Even  
4 Marlex mesh was grandfathered in. So yeah, it was, but  
5 see, there's a difference in structure between a mesh  
6 and a suture. The material was approved --

7 BY MR. HUTCHINSON:

8 Q I understand.

9 A -- and surgical mesh was what the  
10 grandfathered device --

11 Q But stick with me. The original Prolene mesh  
12 was made of the exact material that FDA had already  
13 approved as safe and effective, correct?

14 A For a suture, yes, sir.

15 Q Okay, fine, and then ultimately, FDA  
16 classified surgical mesh, including Prolene mesh, as a  
17 Class II device.

18 A Yes.

19 Q You know that.

20 A Yes.

21 Q Okay, and that occurred in the 1990s, based  
22 upon your review?

23 A It was late 1980s, early 1990s, somewhere in  
24 there.

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1 Q Okay, and FDA reached that decision after  
2 recommending, or -- after considering recommendations of  
3 three panels of experts, correct?

4 A You mean their classification panels. Yes,  
5 their standard classification panel. The panel  
6 recommended that surgical mesh should be cleared as a  
7 Class II device, and FDA did accept that.

8 Q And those panels held open meetings?

9 A I believe so. They're public, the  
10 information.

11 Q Did you go to any of those?

12 A No. I think it predated my time at the FDA.

13 Q I'm going to hand you what we'll mark as  
14 Exhibit 11 to your deposition. If you can put that 10  
15 back there?

16 A Yes, sir. I got more than 10. Are you going  
17 to do the --

18 Q Just set it aside. We'll...

19 A Got it. Yeah, 1982.

20 (Whereupon, Exhibit 11 was marked for  
21 identification.)

22 BY MR. HUTCHINSON:

23 Q So you've seen this document before, correct?

24 A Yes, sir, talking about mesh.

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1 Q And in fact, you relied on it in forming your  
2 opinions.

3 A At various times, yes, sir.

4 Q And if we look at page 17 -- well, first of  
5 all, this is a proposed rule classifying Prolene mesh as  
6 a Class II device, correct?

7 A Right, that's how that works. You have to  
8 come out with a proposed rule, first.

9 Q Okay, and look with me on page 17.

10 A Yes, sir.

11 Q It says,

12 "Summary for reasons for recommendation:

13 The Panels recommend that surgical meshes be  
14 classified into class II (performance  
15 standards) because the Panels believe that the  
16 device has an established history of safe and  
17 effective use."

18 Did I read that correctly?

19 A Yes, sir.

20 Q Okay. Do you agree with that?

21 A Yes, knowing the history of what they were  
22 reviewing, because they're talking about going -- the  
23 original surgical mesh was actually for reinforcing soft  
24 tissue, bone, and it was used in trauma patients in

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1 Vietnam, and it wasn't always permanently placed. It  
2 was transient. So yeah, I believe that there had been a  
3 history of surgical mesh use in the past.

4 Q Well, but let's be clear. You agree with the  
5 expert panels that the FDA employed in that the device  
6 has an established history of safe and effective use.  
7 That's something you agree with, correct?

8 A Based on the history --

9 Q I'm sorry, is that a yes?

10 A Yes. Knowing --

11 Q I'm sorry, is that a yes?

12 A Yes, knowing the documents they're reviewing,  
13 yes. It's not anything to do with surgical, for  
14 urological uses.

15 Q And FDA then classified Prolene mesh as a  
16 Class II device in the latter part of 1998 -- I'm sorry,  
17 1988.

18 A Correct, and then they have performance  
19 standards, which FDA never issued. So there was an  
20 expectation that FDA was going to issue performance  
21 standards for different devices, and they didn't.

22 Q And it's been in use ever since, right?

23 A Yes.

24 Q Okay. So I want to hand you what we'll mark

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1 as Exhibit 12 to your deposition, Dr. Parisian.  
 2 A Okay. Are we done with this?  
 3 Q Yeah, you can put it in that stack.  
 4 A Got it. Yes.  
 5 (Whereupon, Exhibit 12 was marked for  
 6 identification.)  
 7 BY MR. HUTCHINSON:  
 8 Q And you've seen this, or -- this is the July  
 9 of 1990 order down-classifying sutures, right?  
 10 A Yes, sir.  
 11 Q And this is a document that you relied on in  
 12 forming some of your opinions?  
 13 A About the history of mesh, yes, sir.  
 14 Q Correct. And if you look at the first  
 15 paragraph, it says, "FDA concludes....," are you with me?  
 16 A And this is in response to a petition by U.S.  
 17 Surgical. U.S. Surgical wanted to -- Ethicon wasn't --  
 18 Q Look at the first paragraph.  
 19 A All right.  
 20 Q It says, "FDA concludes....," you see that?  
 21 A The first --  
 22 MR. OLIVEIRA: Second sentence.  
 23 THE WITNESS: Second sentence. Yes, sir,  
 24 I see it. Um-hum, suture.

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1 BY MR. HUTCHINSON:  
 2 Q Actually, turn to the last page for me.  
 3 Robert Sheridan, he's on this letter on behalf of the  
 4 FDA. You see that?  
 5 A He signed it on behalf of Office of Device  
 6 Evaluation, so he --  
 7 Q And you worked for FDA.  
 8 A Yes, sir.  
 9 Q Did you ever work with Robert?  
 10 A Yes, sir.  
 11 Q Did you know him?  
 12 A You know, I never worked with him. He was at  
 13 the center when I was there, and then he retired shortly  
 14 after I was there, so....  
 15 Q Is he a competent individual?  
 16 A I don't know.  
 17 Q You don't know?  
 18 A Well, I know his background is totally  
 19 different. He's an administrative person, no clinical  
 20 background, but he was in management at the FDA.  
 21 Q If we look at page 12, ETH.MESH09634675. Do  
 22 you see that?  
 23 A Okay. Page 12?  
 24 Q Correct.

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1 A Where are you? Based on -- what paragraph?  
 2 I'm on page 12.  
 3 Q Okay. The second from the bottom paragraph,  
 4 it says, "In this matter....," do you see that?  
 5 A Um-hum.  
 6 Q It says,  
 7 "...significant publicly available  
 8 information indicates that the existing  
 9 nonabsorbable polypropylene surgical sutures  
 10 are generally safe and effective."  
 11 Did I read that right?  
 12 A Yes, sir.  
 13 Q And do you agree with that statement?  
 14 A Yes, sir.  
 15 Q Okay, so let's just be clear that you agree,  
 16 as an FDA expert in this case, that the polypropylene  
 17 sutures were safe and effective, correct?  
 18 A Yes, sir.  
 19 Q And also, if you turn with me to page 7 of  
 20 this document, bottom paragraph, and the last sentence  
 21 there says,  
 22 "...and that the polymer's degradation  
 23 proceeds slowly and is generally not  
 24 considered clinically significant under most

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1 circumstances of use."  
 2 Did I read that correctly?  
 3 A That's what it states, yes, sir.  
 4 Q And you agree with that, don't you?  
 5 A That that's what it states?  
 6 Q No, you're agreeing with that statement,  
 7 correct?  
 8 A Let me look at the whole statement.  
 9 MR. LUNDQUIST: Object to form.  
 10 THE WITNESS: This was actually based on the  
 11 time period, in terms of, there's been knowledge about  
 12 suture, different things that cause sutures to oxidize  
 13 and degrade since this time, but this is in 1990. So it  
 14 reflects the information considered in 1990.  
 15 BY MR. HUTCHINSON:  
 16 Q Well, my question is: Do you agree with that  
 17 statement?  
 18 A That it reflects 1990.  
 19 Q Do you agree that the degradation is  
 20 clinically insignificant under most circumstances of  
 21 use? You agree with that?  
 22 A They're talking about suture.  
 23 Q Right.  
 24 A So in terms of --

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1 Q I understand. I understand. I'm asking if  
 2 you agree with that.  
 3 MR. LUNDQUIST: Object to form.  
 4 THE WITNESS: For suture, yes.  
 5 BY MR. HUTCHINSON:  
 6 Q And let's be clear. The mesh is made up of  
 7 the exact type of material that suture is, correct?  
 8 A That's not what they're talking about, though.  
 9 Q I'm not --  
 10 A They're talking only about suture.  
 11 Q Stick with me. Stick with me.  
 12 A But you can't generalize from here.  
 13 Q I understand. Move to strike as  
 14 nonresponsive. Stick with me.  
 15 You will agree that the suture is made up of  
 16 the exact -- I mean, the mesh is made up of the exact  
 17 material as what the suture is made of, correct?  
 18 MR. LUNDQUIST: Form.  
 19 THE WITNESS: Yes, they're both polypropylene,  
 20 but they're not the same. This is suture, which is a  
 21 different area, surface area, than mesh. And it's a  
 22 different indication, because people usually tend to use  
 23 multiple sutures in a surgical site. So one suture may  
 24 not be quite as important.

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1 BY MR. HUTCHINSON:  
 2 Q Let's look at page 12, bottom paragraph, last  
 3 sentence. Are you with me?  
 4 A Page 12, bottom paragraph. We're flipping  
 5 through the -- okay, bottom paragraph, all right.  
 6 Q It says,  
 7 "...determination of comparable safety  
 8 and effectiveness of future nonabsorbable  
 9 polypropylene surgical suture and marketed  
 10 sutures can be made in the context of a  
 11 pre-market notification under Section  
 12 510(k)...."  
 13 Did I read that right?  
 14 A Well, it's -- yes, this is classified in a  
 15 510(k), for suture.  
 16 Q And that means that the FDA uses a 510(k)  
 17 paradigm to determine comparable safety and  
 18 effectiveness.  
 19 MR. LUNDQUIST: Form.  
 20 THE WITNESS: For suture, yes, sir.  
 21 BY MR. HUTCHINSON:  
 22 Q Okay, and it's fair to say that the mesh that  
 23 Ms. Garcia received was made up of small sutures that  
 24 FDA previously approved as safe and effective.

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1 MR. LUNDQUIST: Form.  
 2 THE WITNESS: No, her mesh is not sutures.  
 3 BY MR. HUTCHINSON:  
 4 Q It's made of the exact same material that was  
 5 previously approved by FDA as safe and effective,  
 6 correct?  
 7 MR. LUNDQUIST: Form.  
 8 THE WITNESS: Polypropylene is approved and  
 9 cleared. I've never said anything -- as a suture --  
 10 BY MR. HUTCHINSON:  
 11 Q I understand.  
 12 A -- but there's differences in risk between a  
 13 mesh and a suture, and --  
 14 Q But my question -- stick with me. My question  
 15 is: The mesh that Ms. Garcia received is made of the  
 16 exact same material that FDA had already approved as  
 17 safe and effective, correct?  
 18 MR. LUNDQUIST: Form.  
 19 THE WITNESS: So? I mean, that's --  
 20 BY MR. HUTCHINSON:  
 21 Q I'm sorry, just a yes or no, and then go on  
 22 and explain your answer.  
 23 MR. LUNDQUIST: Form.  
 24 THE WITNESS: Yes, it's made of polypropylene,

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1 but that's really irrelevant, because this is talking  
 2 about suture, and this document is basically, so FDA is  
 3 justifying why they're not going to come out with  
 4 mandatory performance standards for sutures, because  
 5 they were saying that they thought it was low risk, the  
 6 suture material. So that's what this document is  
 7 saying.  
 8 But yes, but just because things are made of  
 9 the same material doesn't mean the risks are potentially  
 10 the same in a human being.  
 11 BY MR. HUTCHINSON:  
 12 Q Dr. Parisian, you're familiar with the Safe  
 13 Medical Device Act of 1990, correct?  
 14 A Yes.  
 15 Q And you'll agree that it added to the 510(k)  
 16 application process a new section called Summary of  
 17 Safety and Effectiveness?  
 18 A Yes, sir.  
 19 Q Okay, so the 510(k) process, at least in part,  
 20 deals with safety, correct?  
 21 MR. LUNDQUIST: Object to form.  
 22 THE WITNESS: Yes, but the safety based on the  
 23 predicates, not on the device itself, because it hasn't  
 24 been marketed.



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1 BY MR. HUTCHINSON:

2 Q Have you ever -- and by the way, let's talk  
3 about your book for a minute. You wrote a book called  
4 "FDA Inside and Out," is that correct?

5 A Yes, sir.

6 Q That was published about Fast Horse Press?

7 A Yes, which is my company.

8 Q You're the only owner of that company, aren't  
9 you?

10 A It doesn't even exist as a company, but yes,  
11 I was the only person -- my husband, I think, took the  
12 money for the books, and so -- but it doesn't even exist  
13 anymore.

14 Q I'm sorry, explain that to me. How can you be  
15 the owner of a company that doesn't exist?

16 A Well, it's not -- it's a doing business --

17 Q Just explain to me, please.

18 A From a legal point of view, it's a doing  
19 business under the name, but it's under my company, my  
20 corporation, Medical Device Assistance, which is now  
21 MD Assist, Inc. So it's now like a facet of that group.

22 Q Is this still the only book that Fast Horse  
23 Press has published?

24 A Yes, and we don't even sell them anymore. So

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1 medical libraries that have it, and people have it.

2 I don't know how many people have it. So it's in  
3 circulation. You can get it on Amazon but, you know,  
4 I don't know how many are out there.

5 BY MR. HUTCHINSON:

6 Q If I were to call Fast Horse Press, who would  
7 answer the telephone?

8 A Nobody, because I believe Fast Horse Press  
9 used to be in Front Royal, Virginia, so there is no Fast  
10 Horse Press.

11 Q Do you -- during your review of this case, did  
12 you review the 510(k) for modified Prolene mesh?

13 A I have reviewed -- you mean in terms of the  
14 surgical mesh for modified Prolene mesh? Yes, I've  
15 reviewed certain, like, Dynamesh, yes, there's mod- --  
16 yes.

17 Q No, I'm talking about the 510(k), K962530, for  
18 modified Prolene mesh. Did you review that?

19 A At one time I did, yes, sir.

20 Q And that would be on your reliance list,  
21 correct?

22 A I don't know if it would be or not, because  
23 I've reviewed it for other things that I've reviewed the  
24 Prolene mesh.

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1 we don't sell them. I mean...

2 Q Who gets -- how many books did this -- did you  
3 sell of this FDA Inside and Out?

4 A Not that many. I mean, I think we originally  
5 had -- I don't know, probably less than a thousand, but  
6 we're not selling them anymore.

7 Q I'm sorry?

8 A Other people sell them. We've given books to  
9 other people to let them sell. So I don't know how many  
10 have been sold.

11 Q You don't sell this book anymore, fair enough?

12 A I don't, that's correct.

13 Q Okay, and why not?

14 A Because I don't have time to fool with it.  
15 Other people have been willing to sell it. The price  
16 we've allowed them to reduce it to whatever -- it was --  
17 so I don't sell it. It's not like it was a money  
18 winner, it was never meant to.

19 Q Does Fast Horse Press still publish this book?

20 A No, it was a one-time publication.

21 Q So this book is not in circulation anymore, is  
22 that correct?

23 MR. LUNDQUIST: Form.

24 THE WITNESS: It is in circulation. There are

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1 Q Do you know what device was used as a  
2 predicate for modified Prolene mesh?

3 A Probably Prolene mesh.

4 Q And FDA -- based on your review, you know that  
5 FDA cleared modified Prolene mesh on August 6, 1996,  
6 correct?

7 A Yes, sir.

8 Q And if somebody wanted a complete picture  
9 about the regulatory history, the 510(k) for modified  
10 Prolene mesh would be relevant.

11 MR. LUNDQUIST: Object to form.

12 THE WITNESS: It could be, at some point when  
13 you go -- I think even in my pile I have documents of  
14 510(k)'s that I've pulled, so I wouldn't just look at  
15 TVT. I'd look at the components.

16 BY MR. HUTCHINSON:

17 Q So the predicate was Prolene mesh.

18 A Yes, sir.

19 Q And it's that the same Prolene mesh that was  
20 grandfathered in as safe and effective.

21 A Yes, sir.

22 Q And FDA found that modified Prolene mesh was  
23 substantially equivalent to Prolene mesh, correct?

24 A Based on what the company told them. The FDA

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1 didn't look at it. They just go on what the document is  
2 that the company sends in, and I don't believe that that  
3 was cleared as a -- for SUI. It was cleared for filling  
4 in spaces that need to have some kind of strengthening,  
5 more surgical hernias and abdominal hernias.

6 Q That's your testimony for modified Prolene  
7 mesh, Dr. Parisian?

8 A I don't recall, but --

9 Q Wait a minute. I'm just asking, yes or no --

10 A I don't know.

11 Q -- is that your testimony for modified Prolene  
12 mesh?

13 A I don't recall that 510(k), in terms of, if it  
14 was specially for SUI.

15 Q And Dr. Parisian --

16 A And the reason I say that is because there are  
17 slings that were made for sacrocolpopexy that actually  
18 had Prolene, people were using surgical mesh. So  
19 I don't recall.

20 Q And Dr. Parisian, you definitely reviewed the  
21 510(k) for TVT, didn't you?

22 A Yes, sir.

23 Q And FDA cleared TVT on January 28, 1998?

24 A Yes.

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1 from.

2 Q And you've seen that letter before, haven't  
3 you?

4 A Yes.

5 Q Relied on it in support of your opinions?

6 A Yes, they corrected their original approval  
7 for TVT. They did this FDA in 2012 with most of these  
8 SUI products. They changed the product code.

9 Q I'm sorry, they didn't correct anything; they  
10 just changed the product code, correct?

11 A Correct, yes.

12 Q Is that correct?

13 A Yes, that's what I was saying. They changed  
14 the product code.

15 Q And Benjamin Fisher signed this letter from  
16 FDA. Did you work with Ben?

17 A No.

18 Q You're not critical of FDA or Ben Fisher in  
19 any way, are you?

20 A No. No, they're just putting it under a  
21 different code, which is how everything is filed at the  
22 FDA, in terms of product. They gave it its own code.  
23 They took it from FTL, which was surgical mesh, and now  
24 put it over into a code that represents SUI products,

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1 Q And TVT, it's made of the same Prolene mesh  
2 that was grandfathered in as safe and effective, right?

3 A Yes.

4 MR. LUNDQUIST: Form.

5 BY MR. HUTCHINSON:

6 Q And are you critical of the FDA at all for  
7 clearing TVT?

8 A No, not based on what the process is at the  
9 FDA.

10 Q And you reviewed the updated letter from FDA  
11 dated September 28, 2012, didn't you?

12 A Which letter?

13 Q It's a letter addressed to Mr. Greg Jones at  
14 Ethicon from FDA regarding TVT.

15 A You mean, to change the product code, or the  
16 522? I don't know if I know that letter. Do I get to  
17 see it?

18 Q Sure.

19 (Whereupon, Exhibit 13 was marked for  
20 identification.)

21 BY MR. HUTCHINSON:

22 Q Dr. Parisian, I'll hand you what we'll mark as  
23 Exhibit 13 to your deposition.

24 A Oh, okay. Okay, yes, this is where I got it

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1 which is -- they gave it OTN, which is mesh surgical  
2 synthetic urogynecological for stress urinary  
3 incontinence female multi-incision.

4 Q And you reviewed the TVT-O for this case --  
5 the 510(k) for TVT-O, didn't you?

6 A Yes, sir.

7 Q And FDA cleared 510(k) for TVT-O on  
8 December 8, 2003.

9 MR. LUNDQUIST: Form.

10 BY MR. HUTCHINSON:

11 Q Yes?

12 A Was it 2003? You have it in front of you.

13 Q Is that correct?

14 A Well, they cleared it.

15 Q Huh?

16 A They cleared it, TVT-O.

17 Q And TVT-O is made of the same Prolene mesh  
18 that was grandfathered in as safe and effective?

19 A Yes.

20 Q And the FDA found that TVT-O was substantially  
21 equivalent to TVT, which had already been cleared,  
22 correct?

23 A Correct, that's what -- based on the 510(k),  
24 yes, sir.

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1 Q So that brings us to TVT Secur. FDA cleared  
2 this, TVT Secur, on November 28, 2005.  
3 A Yes, sir.  
4 MR. LUNDQUIST: Form.  
5 BY MR. HUTCHINSON:  
6 Q Predicate was TVT and TVT-O.  
7 A Yes, sir.  
8 Q Both of those had been cleared.  
9 MR. LUNDQUIST: Form.  
10 THE WITNESS: Yes, sir.  
11 BY MR. HUTCHINSON:  
12 Q And TVT Secur is made of the same mesh that  
13 was grandfathered in as safe and effective?  
14 A Yes.  
15 Q And it's made of the exact same material that  
16 FDA approved as safe and effective, correct?  
17 MR. LUNDQUIST: Form.  
18 THE WITNESS: With the NDA back in the 60's,  
19 yes.  
20 BY MR. HUTCHINSON:  
21 Q Okay. So the product that Ms. Garcia received  
22 was made of the same material FDA approved as safe and  
23 effective, correct?  
24 MR. LUNDQUIST: Form.

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1 THE WITNESS: Actually, not totally correct,  
2 because one of the things is, yes, it's a polypropylene,  
3 but then the laser -- the laser cut actually had changed  
4 the mechanical properties of it, but it is the same --  
5 BY MR. HUTCHINSON:  
6 Q I'm talking about the same material. We're  
7 talking about the same material.  
8 A It's the same material, polypropylene.  
9 Q Thank you. Well, no, it's the same material  
10 Prolene, correct?  
11 A Well, that's the trade name, yes, sir.  
12 Q Okay, and you'll agree with me on that,  
13 correct?  
14 A Yes, sir.  
15 Q And the FDA found that TVT Secur was the  
16 substantially equivalent to TVT and TVT-O, correct?  
17 A Based on the information that the company  
18 provided, yes, sir, and they cited a third predicate,  
19 which was the -- was it Gyne Image Sling? -- to address  
20 the FDA's question for additional information. So there  
21 were three predicates for TVT Secur, not two.  
22 Q And if we look at -- do you have -- I'll hand  
23 you what we'll mark as Exhibit 14.  
24 A Thank you.

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1 Q Dr. Parisian, I'm handing you what we'll mark  
2 as Exhibit 14 to the deposition.  
3 A Yes, sir.  
4 (Whereupon, Exhibit 14 was marked for  
5 identification.)  
6 BY MR. HUTCHINSON:  
7 Q This is the 510(k) for TVT Secur, correct?  
8 A Yes. Yes, sir.  
9 Q And you've definitely seen this document  
10 before you walked in here today.  
11 A Yes, sir.  
12 Q Did FDA mess up by telling Ethicon they could  
13 market this device?  
14 MR. LUNDQUIST: Form.  
15 THE WITNESS: Not based on the information  
16 that was provided, that it was substantially equivalent  
17 to TVT-O, TVT, and the third predicate they indicated  
18 eventually.  
19 BY MR. HUTCHINSON:  
20 Q And do you fault FDA at all for sending the  
21 letter dated November 28, 2005 to Ethicon?  
22 A No, it's a cleared device, based on -- and  
23 it's -- based on what they told the FDA, the FDA cleared  
24 it. They regulatory would have had to have cleared it.

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1 Q And if we look at -- are you with me on the  
2 November 28, 2005 letter?  
3 A Okay, let me find that.  
4 MR. LUNDQUIST: It's the first --  
5 THE WITNESS: Yes, right there, first thing,  
6 got it. All right. What do you want?  
7 BY MR. HUTCHINSON:  
8 Q First paragraph that says,  
9 "You may, therefore, market the device,  
10 subject to the general control provisions of  
11 the Act."  
12 And those are the same general controls provisions we've  
13 already talked about.  
14 A Yes, sir.  
15 Q And those are the general controls that  
16 provide FDA with the means of regulating devices to  
17 ensure safety and effectiveness, is that right?  
18 A Yes, to oversee, as the gatekeeper for devices  
19 in the United States, yes.  
20 Q And the general controls refer to  
21 adulteration?  
22 A Yes, sir.  
23 Q And misbranding?  
24 A Right. Can't misbrand, can't adulterate.

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1 Q And they relate to good manufacturing  
2 practices.

3 A Right, that's the manufacturer does that, yes,  
4 sir.

5 Q And all of these general controls relate to  
6 the safety of the device, is that right?

7 A Trying to ensure the safety for the public of  
8 the devices.

9 Q Is that a yes?

10 MR. LUNDQUIST: Form.

11 THE WITNESS: No, they relate to, the product  
12 can be introduced into marketing in the United States.  
13 That's what this letter is for, and it goes on --

14 BY MR. HUTCHINSON:

15 Q I'm talking about general controls.

16 A Then you go to the third paragraph, and you  
17 can't say --

18 Q I'm not there yet. Just stick with me, okay?

19 A Well, general controls --

20 Q All of these general controls -- wait, I don't  
21 want to talk over the court reporter. All these general  
22 controls relate to the safety of the device, correct?

23 A No, they relate to a device that's being  
24 marketed in the United States. A manufacturer has to

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1 comply with all those requirements in order for ensure  
2 that the manufacturer markets a safe and effective  
3 product that's not prohibited by the Act.

4 Q And --

5 A It says, "you." It says, "you." It keeps  
6 saying "you" to the manufacturer, not the FDA. So these  
7 are the general controls, good manufacturing, that the  
8 FDA has set up that manufacturers independently have to  
9 address in terms of their procedures.

10 Q And if we look at Exhibit 14 to your  
11 deposition, this 510(k) for TVT Secur, this is the  
12 information that Ethicon sent to FDA, is that right?

13 A Yes, sir, and then also additional  
14 information. I think that's in this packet.

15 Q And this is the information that FDA  
16 considered before it cleared TVT Secur, correct?

17 A Sure, yes.

18 Q Okay. If you look at -- do you remember who  
19 signed the Truthful and Accuracy Statement?

20 A I think it was a Patricia --

21 Q Hojnoski?

22 A I think it was.

23 Q Do you have any criticism of Patricia  
24 Hojnoski?

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1 A Yes. I don't think it is truthful and  
2 accurate.

3 Q Have you contacted FDA to alert them that  
4 Patricia messed up?

5 A Well, no.

6 Q If you look at page ETH.MESH.07876630 -- are  
7 you with me?

8 A 6630.

9 Q Have you reviewed this document before?

10 A Yes, sir.

11 Q And did Ethicon misrepresent anything to FDA  
12 here?

13 A They didn't represent the change in stretch,  
14 because that's significant in terms of a surgical mesh.  
15 You have to usually characterize the elasticity  
16 principles and burst strength. They didn't describe  
17 that here. They said it's the same material, but the  
18 ends will have this Ethisorb, the Dura Patch.

19 So they didn't tell the FDA this device is  
20 going to be different in terms of the stretchiness and  
21 that would come from the laser cut as opposed to the  
22 mechanical, and that's an important issue in terms of  
23 surgical mesh.

24 Q Look with me to -- on ETH.MESH 715, if you

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1 have that in front of you.

2 A I will in a minute. All right. Yes, okay.

3 Q And this is a Clinical Review done by  
4 Dr. Hector Herrera, correct?

5 A Yes, I helped hire him. So I know him and  
6 I trained him.

7 Q And he's a competent doctor, isn't he?

8 A Um, yes, he is.

9 Q If you trained him.

10 A He is a competent -- he's a urologist by  
11 training, one of the few that they have at the FDA.

12 Q Do you have any criticism of Dr. Herrera?

13 A No, I have a criticism that he wasn't listened  
14 to, but...

15 Q I'm sorry, he wasn't listened to?

16 A As a medical officer, he gives his opinions  
17 and it's up to the rest of the division who's reviewing.  
18 He's not in the same division.

19 Q Was Dr. Herrera diligent and smart?

20 A Yes, I think he's right. They needed to give  
21 data.

22 Q Was he an honest doctor?

23 A Yes.

24 Q And did you work with him at all at FDA?

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1 A Yes, I -- I --  
 2 Q After you hired him.  
 3 A Yes, but he's a part-time, he's an older  
 4 urologist. He was -- he had retired from urological  
 5 practice.  
 6 Q And if you'd look at the next page, 716, last  
 7 paragraph, it says,  
 8 "With the company's response to prior  
 9 deficiencies, I do not have any urological  
 10 clinical issues to preclude approving the  
 11 submission."  
 12 Do you see that?  
 13 A Um-hum.  
 14 Q Did he get it wrong?  
 15 A No, not based on the process, because they  
 16 came up with a subsequent 510(k) that showed that they  
 17 had actually already approved it, the Gyne Ideas  
 18 Minitape, which makes it so the FDA can't really ask for  
 19 clinical studies if they've already got a predicate.  
 20 Q Are you aware of anything Ethicon hid from  
 21 Dr. Herrera or misrepresented to Dr. Herrera?  
 22 A Well, yeah, they misrepresented the European  
 23 experience and the KOLs were not having a good time  
 24 putting this in, and that the IFUs were inadequate and

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1 that document, this is a letter dated October 7, 1988  
 2 from FDA, is that right?  
 3 A Right.  
 4 Q And it's about the same NDA 16374 that we've  
 5 been talking about?  
 6 A Correct --  
 7 Q The Prolene suture.  
 8 A -- and it's been transitioned with the  
 9 Supplement 34 -- you have so many supplements --  
 10 Supplement 34, and it's now being reviewed as a PMA by  
 11 CDRH.  
 12 Q And the page that I referenced you to, that's  
 13 the package insert that Ethicon sent FDA, correct?  
 14 A For Prolene, yes, sir.  
 15 Q And it says, under Actions, "The suture...."  
 16 Are you with me?  
 17 A Yes.  
 18 Q It says,  
 19 "The suture is not absorbed nor is it  
 20 subject to degradation or weakening by the  
 21 action of tissue enzymes."  
 22 Is that correct? That's what it says?  
 23 A Yes, sir, that's what it says.  
 24 Q And that's the exact language in the IFU for

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1 that there were safety issues.  
 2 Now, this is to get cleared. This device got  
 3 cleared. The issue really for Ms. Garcia is  
 4 post-market.  
 5 But they did not -- and they did not tell  
 6 Dr. Herrera about the change in the mesh, the difficulty  
 7 with using the inserter, and they are basing their  
 8 argument on that they're substantially equivalent to TVT  
 9 and TVT-O.  
 10 And so he had to accept, based on what their  
 11 representations were from the expert, the company, that  
 12 they had satisfied his concerns.  
 13 (Whereupon, Exhibit 15 was marked for  
 14 identification.)  
 15 BY MR. HUTCHINSON:  
 16 Q Let's look at what I'll hand you to be marked  
 17 as Exhibit 15 to your deposition, and you have reviewed  
 18 this document before today, haven't you, Dr. Parisian?  
 19 A Let me look at it and make sure.  
 20 Q Okay. Yes?  
 21 A Yes, this is for the PMA, when it was still a  
 22 PMA.  
 23 Q And if you'll look with me on  
 24 ETH.MESH.09634315 -- and by the way, before we get to

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1 TVT Secur about degradation.  
 2 A Correct, I said that it came from the suture.  
 3 Q Right.  
 4 A Came from Prolene suture.  
 5 Q And that exact language was sent to FDA, back  
 6 in 1988 and before that?  
 7 A Yes, it's a PMA supplement for a suture  
 8 material.  
 9 Q I'm sorry, is that correct?  
 10 A Yes, sir.  
 11 Q And that exact language was reviewed by FDA,  
 12 correct?  
 13 A Yes, based on the 1969 clearance, which  
 14 technology and biochem have changed a lot, but yes, that  
 15 is an approved language carried over from the original  
 16 NDA approval.  
 17 Q Correct, and that exact language was approved  
 18 by FDA, correct?  
 19 A As a drug. It wasn't re-approved, it was --  
 20 what was the indication? It was -- because FDA didn't  
 21 go back and re-look. Let me look at the label. They  
 22 wanted to have an updated labeling changes for the size  
 23 7-0 Prolene clear and pigmented sutures. So it was only  
 24 basically to change the labeling for the clear and

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1 pigmented sutures.

2 Q You're not critical of FDA in any way for  
3 approving that language, are you?

4 A No. I don't have the prior label. I have  
5 this label. So I don't know if that actually had  
6 been -- if it had come from the NDA or if it actually  
7 had been changed in this PMA.

8 Q But that exact language is the same language  
9 about degradation in the current TVT Secur IFU, correct?

10 A Right, it's appropriate for a suture.

11 Q If -- let's talk about your experience with  
12 the FDA a little bit. Back 20 years ago when you worked  
13 at the FDA, did they start out to have safe products  
14 cleared?

15 MR. LUNDQUIST: Form.

16 THE WITNESS: Yes. They still do, as far as  
17 I know.

18 BY MR. HUTCHINSON:

19 Q And when you worked at FDA, you didn't want  
20 to -- an unsafe product to be cleared, did you?

21 A There are legal limitations, like there are  
22 products that are unsafe, like Class III devices that  
23 still haven't been classified by FDA, the safety and  
24 efficacy is not known. So you're bound by what the

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1 Q Give me your best estimate.

2 A I don't know. We're talking about many --  
3 I wouldn't be surprised if it was in the hundreds --

4 MR. LUNDQUIST: Form.

5 THE WITNESS: -- in terms of all the different  
6 510(k)'s and supplements and, yeah, changes.

7 BY MR. HUTCHINSON:

8 Q FDA has never recommended any labeling changes  
9 for TVT Secur, has it?

10 A I haven't seen any. I don't know if they have  
11 or not.

12 Q And FDA has never recommended any labeling  
13 changes for any of the TVT family of products, have  
14 they?

15 A I don't know. I mean, I would have to -- only  
16 the FDA and Ethicon would know that.

17 Q What you do know is that FDA has never  
18 determined that TVT Secur labeling was false or  
19 misleading, is that --

20 A Why would they? They never had to review it.

21 Q My question is a yes or no. Then you can  
22 explain.

23 A No, they have not. That doesn't change my  
24 opinions, because they had no reason to ever review it.

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1 requirements are for certain products. You didn't want  
2 to hurt people, you wanted to have the public protected,  
3 but you're also limited in terms of what you can  
4 request.

5 Q When you worked for FDA --

6 A In that period, that got worse even in 1997,  
7 when the Lewis Ferguson actually got passed.

8 Q When you worked for FDA, Dr. Parisian, did you  
9 work alongside competent professionals?

10 A Yes.

11 Q FDA could have refused to clear modified  
12 Prolene mesh, correct?

13 MR. LUNDQUIST: Form.

14 THE WITNESS: They could have, but why would  
15 they?

16 BY MR. HUTCHINSON:

17 Q FDA could have refused to clear TVT or TVT-O  
18 or TVT Secur, correct?

19 MR. LUNDQUIST: Form.

20 THE WITNESS: Yes, they could have.

21 BY MR. HUTCHINSON:

22 Q And do you know how many transvaginal mesh  
23 slings FDA has cleared, sitting here today?

24 A Quite a few.

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1 It's up to Ethicon to have made an adequate label.

2 Q FDA has never determined that the labeling of  
3 any of the TVT family of products is false and  
4 misleading.

5 A That's correct. They've done some other  
6 action where they send out a safety -- a public health  
7 notification, so it's actually taking it kind of one  
8 step higher. FDA is actively involved in the labeling  
9 and information being given to physicians and patients.

10 Q And because FDA is actively involved, they  
11 have never determined that the TVT Secur device was  
12 misbranded, have they?

13 A I don't think they've ever reviewed it to look  
14 at that. That would be a --

15 Q Well, I'm not talking about what they  
16 reviewed. I need a yes or no: FDA has never determined  
17 that TVT Secur device was misbranded.

18 A That is correct, because they've never looked  
19 at it, as far as I know.

20 Q And in fact, FDA has never considered or  
21 determined that any of the TVT family of products have  
22 been misbranded, have they?

23 A Not that I'm aware of.

24 Q Misbranding, that's a specific finding by FDA.



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1 Yes?

2 A No, it's --

3 Q No?

4 MR. LUNDQUIST: Form.

5 THE WITNESS: It's just -- it's a legal

6 finding by the FDA, but it's described in the Act for  
7 the manufacturer, in terms of misbranding, adequate  
8 instructions for use of warnings. It puts it on the  
9 manufacturer, not the FDA, to make sure that they're not  
10 misbranded, and that even in the approval letters, the  
11 clearance letter you showed me before, it said it's up  
12 to the manufacturer to ensure that they don't misbrand,  
13 adulterate.

14 So it's under -- and we're talking 21 U.S.C.  
15 352. So that's the manufacturer's job. It's not up to  
16 the FDA. The FDA may fine somebody who's misbranded and  
17 bring charges or make a warning letter saying that, but  
18 it's really the manufacturer to ensure they don't  
19 misbrand their product.

20 MR. HUTCHINSON: Move to strike as  
21 nonresponsive.

22 Q FDA -- strike that. Misbranding is a legal  
23 finding by FDA, correct?

24 MR. LUNDQUIST: Form.

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1 Q It could make the manufacturer take the  
2 product off the market, can't it?

3 A Only under certain requirements. It's the --

4 Q I'm sorry, is that a yes?

5 A Under certain requirements.

6 Q Wait --

7 A No, I can't answer yes or no --

8 Q Okay.

9 A -- because they're --

10 Q Well, wait just a minute, let me talk.

11 I don't want to talk over the court reporter, okay?

12 If FDA believes that a product is misbranded,  
13 it can tell the manufacturer, or make the manufacturer  
14 take the product off the market, correct? Yes or no,  
15 then you can explain.

16 MR. LUNDQUIST: Form.

17 BY MR. HUTCHINSON:

18 Q That's something the FDA can do, yes?

19 A They can technically do it, but rarely do it,  
20 because it takes --

21 Q Move to strike as nonresponsive.

22 A Well --

23 Q They can do it, can't they?

24 A They can, but technically, they don't. They

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1 THE WITNESS: Well, in two components.

2 It's --

3 BY MR. HUTCHINSON:

4 Q Is that -- I'm sorry. You can explain your  
5 answer, but I need you to say yes, yes or no.

6 A I'm going to say I can't say yes or no,  
7 because one, I'm not an attorney and you're asking me a  
8 legal decision.

9 Q Well, I'm just using your words.

10 A No, but in terms of a manufacturer, in terms  
11 of the Act and as a consultant, I consult with  
12 manufacturers as to whether they've misbranded in terms  
13 of the requirements for adequate instructions and  
14 warnings.

15 So there's two different components: Are you  
16 misbranding? The FDA may make a legal decision or it  
17 may not. The manufacturer is the gate that should  
18 determine misbranding.

19 Q But if the FDA believes that a product is  
20 misbranded, it can make the manufacturer change the  
21 label, can't it?

22 A No.

23 Q No?

24 A No.

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1 would rather get voluntary compliance. Like, they will  
2 send a warning letter. A warning letter will say you're  
3 misbranding. There's no legal action, but it's a  
4 notification that the FDA considers you misbranding.  
5 They're not going to take the product off the market  
6 because of misbranding. They're going to -- the  
7 manufacturer is -- it's assumed that the manufacturer  
8 won't want to not comply with the Act --

9 Q Let's go back --

10 A -- notification. So they did voluntarily  
11 comply --

12 Q Let's get -- let's go back to FDA. The FDA  
13 never concluded that Ethicon had failed to provide  
14 safety information to FDA, did it?

15 MR. LUNDQUIST: Form.

16 THE WITNESS: I don't know. All we can go on  
17 is what the FDA has put in writing. We don't know what  
18 the FDA concluded, but they did ask for a 522 study and  
19 the company chose not to do it.

20 BY MR. HUTCHINSON:

21 Q FDA never concluded that the TVT Secur's  
22 labeling was inconsistent with the medicine or science.

23 A No, that's not correct. In terms of the  
24 public health notification, they looked at the entire

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1 industry --

2 Q Let's talk about the Secur, okay?

3 A Well, they didn't focus on the Secur, they

4 talked about the SUI industry in terms of mesh --

5 Q All right, so let's --

6 A -- and they re-classified it.

7 Q Stick with me, let's stick with my question.

8 On TVT Secur's labeling, FDA never concluded that that

9 labeling was inconsistent with medicine or science.

10 MR. LUNDQUIST: Form.

11 THE WITNESS: You know, I don't know what FDA

12 concluded other than they asked for a 522 post-market

13 safety study.

14 BY MR. HUTCHINSON:

15 Q FDA never requested that TVT Secur be

16 withdrawn from the market.

17 A That's true.

18 Q And FDA never declared that TVT Secur was

19 illegally marketed.

20 A That's true, it was cleared. I've never said

21 it was illegally marketed. I'm saying it wasn't

22 marketed -- the cleared device, in terms of the

23 clearance.

24 Q When we talk about the 522 order, you've

Page 239

1 reviewed that, is that right?

2 A Yes.

3 Q That has nothing at all to do with a recall,

4 does it?

5 A No, no, it's to get post-market safety

6 information, long-term data, to add to the label, update

7 the label, which is one of the things that I said needed

8 to be done.

9 Q A 522 order has nothing to do with punishing a

10 company, does it?

11 A No, and it's usually industry-wide, in terms

12 of, the 522 was issued to all the surgical mesh industry

13 for their products.

14 Q And this 522 order, it was industry-wide,

15 wasn't it?

16 A Yes, sir.

17 Q And it was sent to all manufacturers of mini

18 slings?

19 A Right. To continue marketing, right.

20 Q Not just Ethicon.

21 A That's right.

22 Q And about -- do you know how many companies

23 received -- different companies received a 522 order?

24 A Quite a few, because every product had to have

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1 a 522 order.

2 Q My question is: Do you know how many

3 companies received a 522 order?

4 A No.

5 Q Would it surprise you if it was over 25?

6 A I thought it was more than that. So no, it

7 wouldn't surprise me if you just say 25.

8 Q In fact, do you know that FDA issued over 100

9 522 orders?

10 A See, that's what I was thinking more, yes,

11 sir.

12 Q So Ethicon just wasn't just singled out on

13 this 522 order, were they?

14 A No, no, the entire industry was, particularly

15 for the single-incision sling.

16 Q You don't know why Ethicon stopped making TVT

17 Secur, do you?

18 MR. LUNDQUIST: Object to form.

19 THE WITNESS: I do based on the documents, in

20 terms of the failure of the product and the safety

21 issues. They said they de-commercialized it, but

22 actually it was less safe -- it was less safe than

23 TVT-O. There was no real advantage for a physician to

24 use TVT as compared no TVT-O, in terms of the potential

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1 risk. The Australian physicians didn't even want to be

2 re-trained in it, and it was not -- it was not a big

3 seller. Physicians had stopped using the product.

4 So it was a safety issue. It should have been

5 recalled long before Ms. Garcia was actually implanted,

6 but they chose not to go ahead with the 522 study based

7 on saying the complexity of the study.

8 BY MR. HUTCHINSON:

9 Q Dr. Parisian, let's talk about the MDRs for

10 just a minute and your prior testimony about MDRs.

11 You know the difference between an MDR and an

12 issue report, don't you?

13 A Sure. An MDR is filed by the company.

14 Q And an issue report is not filed by the

15 company, is it?

16 A No.

17 Q And did you review any issue reports in this

18 case?

19 A Not specifically called issue reports. Are

20 you talking about CAPA reports, when the company is

21 looking at safety issues?

22 Q Have you ever looked at Ethicon's policies and

23 procedures for monitoring medical devices?

24 A At various different litigations I have, yes.

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1 Q Okay, I'm talking about for this litigation.  
 2 That's not in your reliance material, is it?  
 3 A No, that's in my training of having been  
 4 involved with Ethicon products in terms of marketing.  
 5 The only thing I saw was a 15 to 20 percent ceiling in  
 6 terms of complaints, and they tend to have an acceptable  
 7 minimum that can be filed every month in terms of  
 8 things -- it goes along with --  
 9 Q How long ago has it been since you looked at  
 10 Ethicon's policies and procedures for monitoring medical  
 11 devices? How many years?  
 12 A I'd say, maybe two.  
 13 Q You did that in the context of other  
 14 litigation?  
 15 A Yes, sir.  
 16 Q But you didn't do that in the context of this  
 17 case, is that right?  
 18 MR. LUNDQUIST: Form.  
 19 THE WITNESS: No, sir.  
 20 BY MR. HUTCHINSON:  
 21 Q Am I correct?  
 22 A Yes, sir.  
 23 Q Are you intending to offer any opinions that  
 24 Ethicon received a product complaint and did not

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1 BY MR. HUTCHINSON:  
 2 Q Well, stick with my question.  
 3 MR. LUNDQUIST: She is answering your  
 4 question.  
 5 THE WITNESS: No, in terms of the volume of  
 6 complaints that are being received and discussed  
 7 internally, the MDRs that I pulled up are not consistent  
 8 with that same pattern. So we know there were things  
 9 not being filed.  
 10 I haven't gotten to go through the complaint  
 11 files specifically and look at them in terms of failure  
 12 to file, but I haven't seen Mrs. Garcia's MDR. There  
 13 should be an MDR filed for Ms. Garcia, and I hadn't seen  
 14 that at that point in time. I don't -- I don't know if  
 15 anyone knows where it is, but there should be something.  
 16 So I can't talk about it without having -- knowing that  
 17 she actually had one filed.  
 18 MR. HUTCHINSON: Move to strike as  
 19 nonresponsive.  
 20 Q Dr. Parisian, are you offering any opinion  
 21 that Ethicon received a product complaint and didn't  
 22 adequately or appropriately report it to FDA?  
 23 MR. LUNDQUIST: Form.  
 24 THE WITNESS: I think I've explained that at

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1 appropriately report it to FDA?  
 2 MR. LUNDQUIST: Form.  
 3 THE WITNESS: The only way I could do --  
 4 BY MR. HUTCHINSON:  
 5 Q Hold on just a minute. I'll let you explain  
 6 your answer, but start with yes or no, and then explain  
 7 for me, please, ma'am.  
 8 A At this point in time, I would say no.  
 9 Q Okay.  
 10 A Because I haven't been given specific  
 11 complaint files, which you know is different than an  
 12 MDR. So the only way to know if something wasn't filed  
 13 is you have to go through each complaint file and see if  
 14 it actually was filed as an MDR. So that's why I'm not  
 15 planning to do that, because I haven't received all the  
 16 complaint files.  
 17 Q So fair enough. As we sit here today, you  
 18 have no opinion whatsoever that Ethicon received a  
 19 product complaint and didn't adequately report it to  
 20 FDA.  
 21 MR. LUNDQUIST: Objection.  
 22 THE WITNESS: Well, I do. In terms of the  
 23 numbers of MDRs, we know that they're receiving  
 24 complaints. A specific --

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1 this point in time I haven't received complaint files,  
 2 which I can do, but I haven't been asked to do that, and  
 3 in Ms. Garcia's point, I haven't specifically received  
 4 her MDR.  
 5 BY MR. HUTCHINSON:  
 6 Q Are you testifying that Ethicon withheld  
 7 anything from FDA?  
 8 A No -- well, in terms of, did they fully  
 9 communicate so that FDA could fulfill its role, I don't  
 10 believe they did, as I talked about, in the 510(k).  
 11 I don't think the risk information came through --  
 12 Q I'm not talking about 510(k)'s. Stick with me  
 13 for just a minute. I'm talking about product  
 14 complaints, MDRs, okay?  
 15 A Well, based on my review, my really  
 16 superficial review, there was not the type of MDRs that  
 17 you would expect to see from the company documents.  
 18 Q My question is: Are you testifying, or do you  
 19 have any opinions, that Ethicon withheld anything from  
 20 FDA regarding product complaints? Yes or no.  
 21 MR. LUNDQUIST: Object, form.  
 22 THE WITNESS: I think I've answered it,  
 23 based -- it will have to be a very general, that in  
 24 terms of the documents I'm seeing, particularly in 2007,

<p style="text-align: right;">Page 246</p> <p>1 the MDRs are not there, in terms of, filed with the FDA.</p> <p>2 BY MR. HUTCHINSON:</p> <p>3 Q So you think -- so you think FDA -- I'm sorry,</p> <p>4 strike that.</p> <p>5 You think, just because of the numbers of MDRs</p> <p>6 that you're seeing in 2007 --</p> <p>7 A Of premature failure.</p> <p>8 Q -- that Ethicon is not adequately reporting</p> <p>9 product complaints to FDA? Is that your testimony?</p> <p>10 A Based on that --</p> <p>11 Q I'm sorry, is that your testimony?</p> <p>12 A Yes, sir. Based on that information today, to</p> <p>13 actually hone it in, I'd have to look at the complaint</p> <p>14 files and compare them one-to-one as to what you're</p> <p>15 reporting.</p> <p>16 Q And that's something you've not done so far,</p> <p>17 is that correct?</p> <p>18 A That's right.</p> <p>19 Q Do you believe that Ethicon had a proper</p> <p>20 safety surveillance department?</p> <p>21 A No, and that's based not on this case, but on</p> <p>22 having seen the other cases that I've been involved in.</p> <p>23 They tend not to report something that's included in the</p> <p>24 label. If the word "erosion" is in the label, it's not</p>	<p style="text-align: right;">Page 248</p> <p>1 Ethicon may have done to violate an MDR reporting</p> <p>2 requirement, correct?</p> <p>3 MR. LUNDQUIST: Object to form.</p> <p>4 THE WITNESS: Only --</p> <p>5 BY MR. HUTCHINSON:</p> <p>6 Q Hold on a minute.</p> <p>7 A Yeah, I cannot, in terms of the documents and</p> <p>8 the reports of perforation, and --</p> <p>9 Q I'm not talking about the documents. I'm</p> <p>10 talking about a specific case example. Can you give me</p> <p>11 one specific case example of a violation?</p> <p>12 A Um-hum.</p> <p>13 MR. LUNDQUIST: Form.</p> <p>14 THE WITNESS: No, and as I said, I haven't</p> <p>15 seen Ms. Garcia's MDR. So there should be an MDR for</p> <p>16 her.</p> <p>17 MR. LUNDQUIST: Are we at a good breaking</p> <p>18 point?</p> <p>19 MR. HUTCHINSON: Give me just one --</p> <p>20 MR. LUNDQUIST: Okay, we've been going --</p> <p>21 that's fine, whatever you need.</p> <p>22 MR. HUTCHINSON: Give me five minutes?</p> <p>23 THE WITNESS: Sure.</p> <p>24 MR. LUNDQUIST: Whatever you want.</p>
<p style="text-align: right;">Page 247</p> <p>1 going to be reported by the procedure. So I would need</p> <p>2 to look at that in more depth, but at this point in</p> <p>3 time, the information suggests that they're not</p> <p>4 adequately surveilling, or -- updating physicians and</p> <p>5 FDA on the risk that's being reported personally.</p> <p>6 Q Can you tell me name of a person who you think</p> <p>7 did something wrong at Ethicon's post-market</p> <p>8 surveillance group?</p> <p>9 A I don't think anybody did anything wrong.</p> <p>10 I think that --</p> <p>11 Q Hold on just a minute. I'm sorry, can you --</p> <p>12 A I don't have a person's name that --</p> <p>13 Q Okay.</p> <p>14 A -- did something wrong. I think that --</p> <p>15 Q Can you tell me the name -- hold on just a</p> <p>16 minute -- can you tell me the name of anybody at</p> <p>17 Ethicon's post-marketing surveillance group that did</p> <p>18 something well?</p> <p>19 A I don't know any of the names in that group,</p> <p>20 and the issue is that they're following procedures, and</p> <p>21 Ethicon has unique procedures in terms of filing of</p> <p>22 MDRs.</p> <p>23 Q So you can't give me, sitting here today, you</p> <p>24 can't give me a specific example of anything that</p>	<p style="text-align: right;">Page 249</p> <p>1 THE WITNESS: Go for it.</p> <p>2 BY MR. HUTCHINSON:</p> <p>3 Q Let's talk about your device work with</p> <p>4 MD Assist. That company's still in existence?</p> <p>5 A Yes, sir.</p> <p>6 Q You're the sole shareholder?</p> <p>7 A No, my husband is, too.</p> <p>8 Q You and husband own it, right?</p> <p>9 A Yes, he gets all the monies, I get all the</p> <p>10 work. We won't tell him.</p> <p>11 Q Has he had a chance to spend any of the money</p> <p>12 you make testifying for plaintiffs?</p> <p>13 A Has he?</p> <p>14 Q Yes.</p> <p>15 A He has all the money. I'm busy doing --</p> <p>16 I don't get...</p> <p>17 Q When is the last --</p> <p>18 A He's an anesthesiologist and does all the</p> <p>19 billing and handles all that stiff.</p> <p>20 Q When is the last time MD Assist did any</p> <p>21 regulatory consulting work for a medical device company?</p> <p>22 A It would have been last year. I had to cut</p> <p>23 off even the manufacturers. I just don't have time and</p> <p>24 I'm trying to cut back.</p>

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1 Q And you don't have time because your full-time  
2 job now is to do the litigation work, like we're here  
3 today on, correct?

4 MR. LUNDQUIST: Object.

5 THE WITNESS: Well, no, I'm trying to retire,  
6 and so I'm trying to not take new issues on. I'm  
7 getting old.

8 MR. OLIVEIRA: I know how you feel.

9 THE WITNESS: And I'll swear to that.

10 BY MR. HUTCHINSON:

11 Q MD Assist has never done any consulting work  
12 for a pelvic floor product, have they?

13 A No, not for a pelvic floor.

14 Q MD Assist has never had a surgical mesh  
15 product approved by FDA.

16 A They're not approved --

17 Q I'm sorry, cleared. Cleared.

18 A That's correct.

19 Q All right. MD Assist has never been involved  
20 with the submission of a 510(k) for a device where it  
21 was surgical mesh.

22 A I believe that's correct.

23 Q And MD Assist has never been involved in the  
24 design of a medical device where part or all of it was

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1 you're -- because I did --

2 BY MR. HUTCHINSON:

3 Q A surgical urogynecological device, correct?

4 A That's correct.

5 MR. HUTCHINSON: All right, so....

6 MR. LUNDQUIST: Five minutes?

7 MR. HUTCHINSON: Will's going to take a break,  
8 so we'll take a quick five.

9 (Deposition in recess from 2:39 p.m. to 2:59 p.m.)

10 MR. HUTCHINSON: Back on the record.

11 Q Dr. Parisian, we're back from a break. You'll  
12 agree that lawyer advertising can stimulate reporting of  
13 adverse events, correct?

14 A It can be one of the things, yes, sir.

15 Q With regard to the adverse events that you  
16 accessed on the MAUDE database, can you identify how  
17 many of those adverse reports were filed by attorneys  
18 representing plaintiffs in mesh litigation?

19 A There were filed by the companies and they  
20 said they were notified by attorneys, so....

21 Q And can you identify how many of those were?

22 A No, sir. But that doesn't mean events don't  
23 happen.

24 Q You'll agree FDA recognizes that submissions

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1 surgical mesh.

2 A That's correct.

3 Q Never been involved in any clinical trial to  
4 evaluate the safety and efficacy of surgical mesh?

5 MR. LUNDQUIST: Object.

6 THE WITNESS: That's correct.

7 BY MR. HUTCHINSON:

8 Q Never been, or -- performed a DDSA for  
9 surgical mesh.

10 A As far as I can recall. You mean at a  
11 company? That's correct.

12 Q Never performed an FMEA for a device where  
13 part of all of it was surgical mesh.

14 A That's correct.

15 Q And in fact, never worked on any medical  
16 device that was designed specifically for a  
17 urogynecological indication.

18 MR. LUNDQUIST: Form.

19 THE WITNESS: Not at the FDA.

20 BY MR. HUTCHINSON:

21 Q Is that correct?

22 MR. LUNDQUIST: Form.

23 THE WITNESS: Other -- you said a surgical --  
24 if you say a surgical, that's correct, because surgical

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1 of an MDR does not mean that the product caused or  
2 contributed to that injury, correct?

3 A That is a statement that is, I think, in the  
4 regulations.

5 Q That's something you would agree to?

6 A Yes. Otherwise, nobody would file any MDRs.

7 Q And you'll also agree, which is consistent  
8 with your testimony before, that oftentimes an MDR is  
9 incomplete.

10 A There are incomplete MDRs filed with the FDA,  
11 yes, sir.

12 Q And you can't draw any conclusions from MDRs  
13 about causation, can you?

14 MR. LUNDQUIST: Object, form.

15 THE WITNESS: It depends on what the MDR says.  
16 I mean, you can't make a blanket statement, but you  
17 can't come up with an incidence rate based on an MDR, on  
18 the MDR database.

19 BY MR. HUTCHINSON:

20 Q Okay, and you have no evidence that Ethicon  
21 failed to report to FDA any adverse event report that it  
22 received.

23 MR. LUNDQUIST: Object to the form.

24 THE WITNESS: Other than that there wasn't any

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1 filing, and I'm seeing all these documents where there's  
 2 erosion failures perforations, and there are no MDRs.  
 3 BY MR. HUTCHINSON:  
 4 Q But no evidence. You have no evidence to  
 5 suggest that, correct?  
 6 MR. LUNDQUIST: Object to form.  
 7 THE WITNESS: I think that is evidence, in  
 8 that the MDRs are only getting filed in 2013. So the  
 9 database is not consistent with the information that the  
 10 company's considering, particularly in 2007, 2008.  
 11 There's nothing about the Australian cases or the German  
 12 cases in the MDR database.  
 13 BY MR. HUTCHINSON:  
 14 Q And that's all the evidence that you have,  
 15 correct?  
 16 A Well, that's significant evidence, because I'm  
 17 looking at the records internally, which is the  
 18 evidence --  
 19 Q Hold on just a minute. I'm not asking for  
 20 significant. I'm asking, is that all the evidence you  
 21 have?  
 22 A That's significant information, yes. That's  
 23 why I would support that the trends in the MDR, not --  
 24 the trends, for the Secur particularly, is not

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1 consistent with the internal picture.  
 2 Q And you can't give us one example of a patient  
 3 having a product complaint and that product complaint  
 4 not being reported to FDA, can you?  
 5 MR. LUNDQUIST: Form.  
 6 THE WITNESS: I'm going to rely --  
 7 BY MR. HUTCHINSON:  
 8 Q I'm sorry?  
 9 A Yes, I think I can.  
 10 Q Tell me the name of that patient.  
 11 A Well, I don't know name of the patient.  
 12 Q Can you give us --  
 13 A I know they --  
 14 Q Hold on just a minute. Stick with me. Can  
 15 you give us one example of a patient who had a product  
 16 complaint and that product complaint did not get  
 17 reported to FDA?  
 18 A The 49 patients in Germany that were not  
 19 reported to FDA in 2007, the Australian patients that  
 20 weren't submitted to the FDA, because the issues and the  
 21 frequency and the severity is not in the labeling in  
 22 2007. So those should have been reported to the FDA.  
 23 Q Let's go to your Exhibit 7, please, and that's  
 24 the patient brochure.

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1 A Exhibit 7, okay, got it.  
 2 Q You've reviewed this and relied on it in  
 3 forming your opinions, correct?  
 4 A Actually, I reviewed the 2008 patient  
 5 brochure. That's in one of my books, here.  
 6 Q And --  
 7 A But this is relevant to Ms. Garcia. It's  
 8 2011.  
 9 Q And this would be -- hold on just a minute,  
 10 Dr. Parisian.  
 11 A Yes, sir.  
 12 Q Dr. Parisian -- Dr. Parisian -- this patient  
 13 brochure that was marked as Exhibit 7 would have been  
 14 the one that Ms. Garcia would have received prior to her  
 15 surgery, correct?  
 16 A Right, I said this would have been the  
 17 relevant one to her, because it's 2011, but I saw 2008.  
 18 Q Do you have any criticisms about this patient  
 19 brochure?  
 20 A Yes, the criticisms are similar to the IFU, in  
 21 terms of, when we were talking about for the physician,  
 22 the types of the warning information.  
 23 I do have one good statement about Ethicon in  
 24 that they did include a heading about risks, basically,

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1 what risks. So that was good. So you asked me before  
 2 for something good, and --  
 3 Q Move to strike as nonresponsive.  
 4 A No, no, I was trying to --  
 5 Q Let's talk about your criticisms to the  
 6 patient brochure that we've marked as Exhibit 7.  
 7 Would you list any criticisms that you have  
 8 about the patient brochure marked as Exhibit 7?  
 9 A Yes. I would reference the same adverse event  
 10 information that's missing in the IFU, the same type of  
 11 information the document discusses on page 19.  
 12 And one of the things that I didn't mention  
 13 before that would be relevant and germane to a woman's  
 14 brochure is the pain on intercourse for her partner,  
 15 that that is a -- either in the physician's IFU or in  
 16 the patient's information, and I think it's also in  
 17 Dr. Miklos' description, so --  
 18 Q So your testimony is that this patient  
 19 brochure should warn about dyspareunia to a woman's  
 20 partner?  
 21 A No -- yes. Oh, yes, in terms of -- not  
 22 dyspareunia, that's her pain, but a male inserting his  
 23 penis can actually feel -- there's been reports of that,  
 24 particularly from Ms. Garcia. So the pain on



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1 intercourse for the partner, a woman needs to know about  
2 that. That's a big issue if you've got a partner and  
3 he's going to have pain every time he has sex with you.

4 Q Let's talk about your criticisms. Have you  
5 told me all of your criticisms about the patient  
6 brochure marked as Exhibit 7?

7 A Well, I tried to simplify it. It's fairly  
8 similar to the types of problems I had with the IFU, in  
9 terms, specifically for the adverse events, the  
10 permanency, that this is not transitory, which is right  
11 there, and I would also refer you to Dr. Miklos, because  
12 he goes through, from a physician's point of view, the  
13 types of information he thinks should be in the label in  
14 terms of what a physician needs to know, and I would put  
15 it in terms a patient could understand.

16 Q Do you remember when we talked about the IFU,  
17 you listed to me at least 28 specific criticisms you  
18 have of the IFU? Do you remember that testimony?

19 A Yeah, I went -- yes, I went through the label,  
20 trying to give you both the opinion and then what kind  
21 of information I would use to correct it.

22 Q And how many specific criticisms do you have  
23 about the patient brochure?

24 MR. HUTCHINSON: Form.

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1 THE WITNESS: Well, the patient brochure is  
2 not a design issue. It actually has indications,  
3 contraindications, precautions. So I would move that  
4 forward in the beginning for a woman, but the design in  
5 terms of the brochure is a little better than the  
6 physician's IFU, but the adverse reaction information  
7 should be the same, again, warning about the permanency  
8 of the issues, just like I described for the physician  
9 IFU.

10 But it has to be written in terms that a  
11 woman, a non-physician, could understand, a lay person  
12 could understand. It's -- it would be an example of  
13 direct consumer labeling. So it needs to be in  
14 information that a consumer could understand.

15 BY MR. HUTCHINSON:

16 Q How many specific criticisms do you have about  
17 the patient brochure?

18 MR. LUNDQUIST: Form.

19 BY MR. HUTCHINSON:

20 Q You listed 28 or more for the IFU. How many  
21 for the patient brochure?

22 MR. LUNDQUIST: Form.

23 THE WITNESS: Okay, one of the things about  
24 this brochure as opposed to the IFU is, this is called a

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1 "family," "TVT family" product. So it really isn't  
2 specific for TVT Secur. The company is aware internally  
3 that there's differences in risks for the TVT Secur  
4 versus the other products --

5 MR. HUTCHINSON: Move to strike as  
6 nonresponsive.

7 Q Doctor, stick with me and listen to my  
8 question.

9 A That's one.

10 Q Okay, that's one. All right, I'm asking you  
11 to quantify, and if you don't understand my question,  
12 please let me know, but I'm asking you to quantify: How  
13 many specific criticisms do you have about the patient  
14 brochure?

15 MR. LUNDQUIST: Object to form.

16 THE WITNESS: I'm thinking. I would put --  
17 just two, I would put the pregnancy information over by  
18 itself --

19 BY MR. HUTCHINSON:

20 Q I'm sorry, did you say two?

21 A Two.

22 Q And what are they?

23 A The pregnancy information would be taken away  
24 as a specific population all to itself, because it

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1 doesn't apply to most women who are getting SUI  
2 procedures.

3 Q What would the second -- I mean, the second --  
4 strike that. What would the second --

5 A Third. Third.

6 Q Well --

7 A First was that it should be separated out as  
8 a --

9 Q Wait a minute. I don't know if you and I are  
10 communicating. I want to know how many specific  
11 criticisms you have about the patient brochure, and  
12 I thought you told me two.

13 A No, no, I told you the second one.

14 Q Okay, all right. So my question is, how many  
15 specific -- I want you to quantify this, and if you  
16 don't understand the question, let me know, but I'm  
17 asking you to quantify, how many specific criticisms do  
18 you have about the patient brochure?

19 MR. LUNDQUIST: Object to form.

20 THE WITNESS: I would say we were up to two.  
21 So I would say, in a short answer, I can do it in -- as  
22 four. So the third criticism would be --

23 BY MR. HUTCHINSON:

24 Q Okay, hold on just a minute. I'll get to that

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1 in a minute, but I want to make sure I understand. You  
 2 have four specific criticisms about the patient  
 3 brochure, correct?  
 4 A Yes.  
 5 Q All right, do you have any others?  
 6 MR. LUNDQUIST: Form.  
 7 THE WITNESS: No.  
 8 BY MR. HUTCHINSON:  
 9 Q All right. So tell me what your four  
 10 criticisms are about the patient brochure.  
 11 A Okay. We've already done one, we've already  
 12 done two.  
 13 Q All right. Number one was the pregnancy.  
 14 A No, no --  
 15 Q I'm sorry. Number one was --  
 16 A That Secur should be separated out, in terms  
 17 of the --  
 18 Q Okay, Secur should be separated out.  
 19 A Because its risk is unique compared to the  
 20 other product.  
 21 Q Wait just a minute. The court reporter is not  
 22 keeping up with us. Number one is, the Secur should not  
 23 be separated out.  
 24 A No, it should.

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1 Q I'm sorry, it should be separated out. The  
 2 second one was pregnancy, right?  
 3 A In its own special population, taken out of  
 4 the --  
 5 Q Okay, what's the third one?  
 6 A The third are the inadequacies of the warnings  
 7 for the user, as I described for the IFU, but in terms  
 8 that a patient could understand.  
 9 Q Okay, and what's your fourth one?  
 10 A The fourth are the adverse events are  
 11 inadequate, just as I described in the IFU; and then  
 12 I would also reference Dr. Miklos' report on page 19,  
 13 where he talks about, from a physician's point of view,  
 14 what information needed to be in the labeling, and  
 15 I would put that all in terms of a label that a patient  
 16 could understand.  
 17 Q And if Dr. Miklos has opinions about the IFU  
 18 and the patient brochure, your opinions about the IFU  
 19 and the patient brochure would be cumulative, wouldn't  
 20 they?  
 21 MR. LUNDQUIST: Form.  
 22 THE WITNESS: Pardon? I don't understand  
 23 that.  
 24 // //

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1 BY MR. HUTCHINSON:  
 2 Q You don't understand?  
 3 A I don't understand what that is, what your  
 4 question is on that.  
 5 Q They would be duplicative. You're giving  
 6 opinions about the same topics.  
 7 A Oh, you mean --  
 8 Q It would be cumulative.  
 9 A Cumulative.  
 10 MR. LUNDQUIST: Form.  
 11 THE WITNESS: I would rely on Dr. Miklos, in  
 12 terms of the information that he as a physician thinks  
 13 should be in the labeling is consistent with the type of  
 14 information I described before, but the -- the adverse  
 15 events --  
 16 BY MR. HUTCHINSON:  
 17 Q Just a minute, stick with me. But that would  
 18 be cumulative, wouldn't it?  
 19 MR. LUNDQUIST: Object to form.  
 20 THE WITNESS: Cumulative, yes, but I don't  
 21 understand why you're asking that.  
 22 BY MR. HUTCHINSON:  
 23 Q If -- when you reviewed the patient brochure,  
 24 did you notice anything that Ethicon did well --

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1 A Yeah.  
 2 Q -- in drafting the patient brochure?  
 3 A I was trying to tell you what they did well,  
 4 but you didn't want to hear it.  
 5 I thought what was good was, from the 2008 to  
 6 the 2011, they actually did add a section, which I think  
 7 they might have wanted to put up front, about risk, and  
 8 I thought that was a good addition in terms of a label,  
 9 on page -- it's not totally complete, but on page 12.  
 10 And some of the information in the risk  
 11 information is not conveyed in the adverse event  
 12 reports. It's not -- they should cover each other. If  
 13 you're describing these particular risks, then some of  
 14 the adverse event reports or adverse events that I'm  
 15 saying is missing should reflect information that they  
 16 put in this risk section. So the risk -- starting the  
 17 risk section was a good thing.  
 18 Q Did you see anything else that Ethicon did  
 19 well in the patient brochure marked as Exhibit 7?  
 20 A Well, they spelled Gynecare and TVT right, but  
 21 I think that --  
 22 Q Anything else?  
 23 A It's a better -- they're improving their label  
 24 since the 2008 label, but they still are not conveying

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1 the specific risks for the TVT Secur, which is different  
 2 than the other products. They're just putting them  
 3 together in the TVT family. Even internally that was  
 4 questioned when the company was saying, are we really  
 5 going to have a TVT family that includes TVT Secur?

6 So I think that that would be my number one,  
 7 but I think it was right to have questions for your  
 8 doctor, but they needed to improve the adverse events to  
 9 make sure that the woman knew that these were permanent  
 10 risks, such as chronic pain, dyspareunia, change in the  
 11 vagina, things like that. And I think I captured that  
 12 before when I talked about the IFU for the physician.

13 Q You're not an expert on Prolene, are you?

14 A What do you mean by "an expert on Prolene"?  
 15 I mean, you've seen I've gone through the regulatory  
 16 history of Prolene, so I don't know if.... There is a  
 17 regulatory expertise that I have on Prolene.

18 Q Would that be the only expertise that you have  
 19 on Prolene?

20 MR. LUNDQUIST: Form.

21 THE WITNESS: I've used Prolene suture, so  
 22 I don't know, what do you mean, in terms of Prolene?

23 BY MR. HUTCHINSON:

24 Q Do you hold yourself out as an expert on

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1 A They wouldn't. They would recommend not using  
 2 it, but they wouldn't recommend removal.

3 Q And they have never recommended not using TVT  
 4 Secur, have they?

5 A I don't know what the NIH -- I haven't looked  
 6 at what the NIH has said about TVT Secur.

7 Q The American College of OB-GYN has never  
 8 recommended removing any mesh product from the market,  
 9 has it? ACOG.

10 A A specific mesh --

11 Q We're referencing ACOG, A-C-O-G.

12 A Not that I recall. They have guidelines, they  
 13 don't talk about removal of a device.

14 Q The American Urogynecologic Society, or AUGS,  
 15 has never recommended removing any mesh product from the  
 16 market, has it?

17 A I believe so. I don't see that that would be  
 18 their role, either.

19 Q I'm correct?

20 A Yes, sir. I said, I believe so.

21 Q And you would agree that a ban on the use of  
 22 synthetic mesh products would prohibit many women from  
 23 accessing treatment options?

24 A A ban, for many indications -- they use

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1 Prolene?

2 A In terms of the regulatory issues that would  
 3 be considered, FDA regulatory, on Prolene.

4 Q And that would be all, is that correct?

5 A As a physician --

6 Q I'm sorry. And that would be all, correct?

7 MR. LUNDQUIST: Form.

8 THE WITNESS: I believe that's the only role  
 9 I would have here in terms of Prolene.

10 BY MR. HUTCHINSON:

11 Q Okay, and --

12 A And as a pathologist and as having looked at  
 13 tissue slides, you know, animal studies, so -- but that  
 14 would be regulatory, too. That would be -- I guess you  
 15 would call that a toxicology point of view.

16 Q The FDA advisory panel has never recommended  
 17 removing any mesh product from the market, correct?

18 A The advisory panel? I believe that's correct.  
 19 They didn't even -- you're talking about advisory panel  
 20 where they talk about SUI and POP? Yes, they asked for  
 21 data.

22 Q The National Institutes of Health has never  
 23 recommended removing any mesh product from the market,  
 24 has it?

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1 surgical mesh for a lot of --

2 Q Stick with my question.

3 A I didn't --

4 Q You would agree that a ban on the use of  
 5 synthetic mesh products would prohibit many women from  
 6 accessing treatment options, correct?

7 A That's a very generic statement. It's not  
 8 the --

9 Q I'm asking you. Correct?

10 A If FDA banned all surgical --

11 Q Just a minute. Wait a minute. I don't want  
 12 to talk over the court reporter.

13 A No.

14 Q You would agree, correct, Dr. Parisian? Yes  
 15 or no.

16 MR. LUNDQUIST: Form.

17 THE WITNESS: Well, let me ask --

18 BY MR. HUTCHINSON:

19 Q I'm the one asking questions today.

20 A I know, I want to answer. I'm asking for a  
 21 clarification.

22 Are you saying -- what I think you're saying  
 23 is, if FDA were to ban surgical mesh, that would deny  
 24 women treatment options, generally? Yes.

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1 Q Let me hand you what we'll mark as Exhibit 16  
2 to your deposition.

3 (Whereupon, Exhibit 16 was marked for  
4 identification.)

5 THE WITNESS: So do the colors have any  
6 indication, on the clips? That's a black.

7 MR. LUNDQUIST: What?

8 MR. HUTCHINSON: I got a black clip. That  
9 means it's a very important document, one I suspect  
10 you'll probably disagree with, but we'll try to -- we'll  
11 try to go through it.

12 Q I've handed you what's been marked as  
13 Exhibit 16 to your deposition. Do you see that?

14 A Yes, sir.

15 Q In fact, this is a document you relied on in  
16 reaching your opinions, is that right?

17 A I've seen this, yes.

18 Q And AUGS, that's an association of surgeons  
19 who treat SUL.

20 A That would be that group, yes, sir.

21 Q Has over 1700 members.

22 A Yes.

23 Q It includes urologists, gynecologists and  
24 urogynecologists, correct?

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1 A Yes, sir.

2 Q And that's what Ms. Garcia has got, right?

3 MR. LUNDQUIST: Object to form.

4 THE WITNESS: Um --

5 BY MR. HUTCHINSON:

6 Q Dr. Parisian --

7 A Let me look at this, because they often make a  
8 differentiation between the SISMUS and the MUS. Let me  
9 just see what they're talking about.

10 Q All I'm asking you is: Is your opinion that  
11 Ms. Garcia got a mid-urethral sling?

12 A Yes, single-incision mid-urethral sling.

13 Q And paragraph 2 says,

14 "The monofilament polypropylene mesh MUS  
15 is the most extensively studied  
16 anti-incontinence procedure in history."

17 Do you agree with that statement?

18 A Where --

19 Q Paragraph 2.

20 A Paragraph 2.

21 Q The bold.

22 A Oh, all the heading. I thought you're talking  
23 about the --

24 Q Do you agree with that statement?

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1 A Right, and it includes the SFU -- SSFU.

2 Q And that's another society, true?

3 A Right, Society of Urodynamics, Female Pelvic  
4 Medicine and Urogenital Reconstruction.

5 Q And you're not a member of either one of  
6 these, are you?

7 A No, sir.

8 Q And if we look on page 2, paragraph one, in  
9 bold it says, "Polypropylene material is safe and  
10 effective as a surgical implant." Do you see that?

11 A Yes, sir.

12 Q Do you agree with that statement,  
13 Dr. Parisian?

14 A Yes, sir.

15 Q Okay, and if we look at --

16 A And look at, they talk about the different  
17 specialties, and they're talking about the general  
18 polypropylene, yes, sir. We've talked -- that it's been  
19 approved, FDA, polypropylene, surgical implant. It can  
20 be a suture, it can be anything.

21 Q And if we look at -- if we look at paragraph  
22 four -- I'm sorry, if we look at paragraph two, the  
23 monofilament polypropylene mesh, MUS, that stands for  
24 mid-urethral slings, correct?

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1 A Yes, that's what the group said at the  
2 advisory panel. The FDA disagreed, that they needed  
3 more safety information, but this group of physicians  
4 said that they were satisfied that it's been studied.  
5 FDA didn't agree with that at the panel meeting or in  
6 its subsequent documents. That's why they're trying to  
7 get data. They didn't ask for a 522 for those products.  
8 They expected the --

9 Q Move to strike as nonresponsive.

10 Paragraph 4 says,

11 "The FDA has clearly stated that the  
12 polypropylene mid-urethral sling is safe and  
13 effective in the treatment of SUL."

14 Do you agree with that statement?

15 MR. LUNDQUIST: Form.

16 THE WITNESS: I think you need to look at what  
17 is said in that paragraph. That's what I would agree  
18 with.

19 BY MR. HUTCHINSON:

20 Q But I'm asking you, do you agree with that  
21 statement?

22 A No, I think you need to look at, the FDA  
23 continues to evaluate it, its use for the treatment, and  
24 will report later, and the FDA says that they have data

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1 up to one year, for multi-incision. This isn't the TVT  
 2 Secur.  
 3 Q Do you disagree that the FDA has stated that  
 4 polypropylene MUS is safe and effective in the treatment  
 5 of SUI?  
 6 MR. LUNDQUIST: Form.  
 7 BY MR. HUTCHINSON:  
 8 Q That's something you disagree with?  
 9 MR. LUNDQUIST: Form.  
 10 THE WITNESS: I agree with what's in the  
 11 paragraph. I don't agree with that statement. The  
 12 FDA's continuing to get data about it. So the paragraph  
 13 is correct, but the statement is, I think, overreaching.  
 14 BY MR. HUTCHINSON:  
 15 Q Um --  
 16 A And if you look at above, in number 1, they  
 17 said that even for surgical mesh, there's no data past  
 18 17 years, in terms of safety. So it's not totally  
 19 proven, and that's what's going on here. FDA is asking  
 20 for data.  
 21 MR. HUTCHINSON: Move to strike as  
 22 nonresponsive.  
 23 Q Dr. Parisian, let's change gears for a minute.  
 24 Have you ever participated in a urogynecological

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1 know.  
 2 Q Have you ever participated as a subject in a  
 3 clinical trial for any type of gynecological product?  
 4 A No. No, I haven't. As a subject, the  
 5 patient?  
 6 Q Yeah.  
 7 A No.  
 8 Q Have you ever tested any type of gynecological  
 9 product in some type of trial?  
 10 A No.  
 11 Q You wrote a book at one point called, "Twin  
 12 Cubs of a White Wolf"?  
 13 A Yes, sir.  
 14 Q And what is that book about?  
 15 A It's a romance novel that I never sold.  
 16 I used the name McLean Thomas and --  
 17 Q Okay, why didn't you use your real name when  
 18 you published it?  
 19 A Because I just felt like -- I registered my  
 20 name. That's why everybody, all the defense firms know  
 21 the name. So I haven't hidden the name, but I just  
 22 didn't use it at the time, and I wrote -- and it's never  
 23 been sold or distributed. Somehow, defense firms have  
 24 found it, I guess, at the Library of Congress and some

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1 clinical trial?  
 2 A No, sir. I haven't participated in one.  
 3 Q Have you ever participated in any clinical  
 4 trial for any medical product?  
 5 A You mean me being a subject? No, I've been --  
 6 MR. LUNDQUIST: No, I don't think that's what  
 7 he's saying.  
 8 She suggesting she's actually a participant  
 9 that, like -- just clarifying the question, here.  
 10 BY MR. HUTCHINSON:  
 11 Q No?  
 12 A No, I've not been in. I did some clinical  
 13 trials back when I was in my hospital days as an ER  
 14 doctor, I remember having to go to IRBs and stuff.  
 15 I don't remember what they were, but they were  
 16 device-type drugs.  
 17 Q My question to you is: Have you ever  
 18 participated in any clinical trial as a participant for  
 19 a medical device?  
 20 A Well, see, I've never been a subject or an  
 21 investigator in a clinical trial that I'm aware of.  
 22 I've reviewed them for the FDA and approved them,  
 23 monitored them, evaluated them, but not been the  
 24 principal investigator. I think that's what you want to

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1 defense blogs have put it online, with -- which I think  
 2 is illegal, but I've never sold it. And it has nothing  
 3 to do with the FDA.  
 4 Q Have you ever -- what is the book about, then?  
 5 A The book is about a mother that lies, that's  
 6 the white wolf, and two people that think that she's  
 7 their mother and she's not.  
 8 Q Is it about an incestuous sexual relationship?  
 9 MR. LUNDQUIST: Form.  
 10 THE WITNESS: No, they're not incestuous.  
 11 That issue is that they're not related at all, and the  
 12 mother is allowing them to think they were. So that's  
 13 where the mother's lying. And I didn't sell it. A lot  
 14 of judges would love it, but I haven't sold it.  
 15 MR. HUTCHINSON: Let me take a quick break.  
 16 (Deposition in recess from 3:29 p.m. to 3:43 p.m.)  
 17 BY MR. HUTCHINSON:  
 18 Q Dr. Parisian, we're back on the record, having  
 19 taken a break. Do you intend to offer any other  
 20 opinions in this case other than the ones we've already  
 21 discussed?  
 22 MR. LUNDQUIST: Object to form.  
 23 THE WITNESS: No. Could I clarify something  
 24 about my book?

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1 BY MR. HUTCHINSON:

2 Q Sure.

3 A That I said judges would like it, I don't mean  
4 the judges would like it. I mean that they're curious  
5 as to why a book about -- not about the FDA, that was  
6 never sold, is always brought up. So I don't know if  
7 they'd like it or not. I wanted to correct that answer.

8 Q Okay, fine. Is that the only romance novel  
9 you've ever written?

10 A Well, it's the only one ever published. The  
11 other one's up in my closet. I'm not going to do that  
12 again.

13 Q Do you recommend doing any -- I mean, I'm  
14 sorry, strike that.

15 Do you plan on doing any work on -- in this  
16 case in the future?

17 A I haven't been asked to.

18 Q Is there any additional work that you believe  
19 that you should do, having now been deposed?

20 A No.

21 Q Have you ever been sued?

22 A No.

23 Q Have you ever filed bankruptcy?

24 A No.

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1 Q Has the Court ever determined that you cannot  
2 give an expert opinion?

3 A One court has, and that would be the Trasylol  
4 decision in terms of Judge Middlebrooks, and then there  
5 was a judge in Arizona here who had a pain pump case who  
6 did not think a FDA expert was necessary, and then there  
7 was a case for Aredia Zometa, where the judge -- I think  
8 Hogan was the name of the case, or the judge, and he  
9 determined that neither FDA expert could participate  
10 because of the way that the filing was.

11 Q Has a court ever excluded you as an expert?  
12 Is that what you're talking about?

13 A Yes, sir, those are the ones.

14 MR. LUNDQUIST: Form.

15 BY MR. HUTCHINSON:

16 Q That would be how many cases?

17 MR. LUNDQUIST: Form.

18 THE WITNESS: That I know of is Trasylol --  
19 yeah, four.

20 BY MR. HUTCHINSON:

21 Q Four. Have you ever been held in contempt of  
22 court?

23 A No.

24 Q Have you ever been charged or convicted of a

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1 crime?

2 A No.

3 Q Have you understood all of my questions?

4 A I've tried to, and I've tried to ask for  
5 clarification.

6 Q Is there anything about the testimony you've  
7 given that you'd like to change?

8 A No.

9 Q Your middle initial is D, as in David?

10 A Yes, it's Dorgan.

11 Q And your husband's name is James W., is that  
12 correct?

13 A Yes, sir.

14 Q You used to live in West Virginia?

15 A I used to live in the western part of  
16 Virginia, in Fort Royal.

17 MR. HUTCHINSON: All right, thank you. No  
18 further questions.

19 THE WITNESS: Yes, sir.

20 MS. FREEMAN: I don't have any questions.

21 MR. LUNDQUIST: I'm going to have a few,  
22 Cynthia.

23 // //

24 // //

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1 EXAMINATION BY MR. LUNDQUIST

2 BY MR. LUNDQUIST:

3 Q Good afternoon, Doctor.

4 A Good afternoon.

5 Q Certainly we've talked about a lot of your  
6 opinions today, but as the designation set forth as  
7 Exhibit --

8 MR. HUTCHINSON: Four.

9 MR. LUNDQUIST: Thank you.

10 Q -- 4 reflects, you're intending to give  
11 opinions consistent with, obviously, your testimony  
12 today in Exhibit number 4, is that fair?

13 A Pardon?

14 Q You're intending to give opinions at trial  
15 consistent with your testimony today and with respect to  
16 Exhibit 4, which would be the designation of experts?

17 A Yes.

18 MR. HUTCHINSON: Objection, leading.

19 THE WITNESS: Yes, sir.

20 BY MR. LUNDQUIST:

21 Q All right. I want to talk about, since we  
22 haven't really discussed, to some extent, the bases for  
23 some of your opinions, Doctor.

24 As I understood your testimony, is it possible



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1 that there could be an instance where the -- where a  
2 polypropylene sling may be appropriate for implantation  
3 if the physician has adequate information to do a  
4 risk/benefit analysis?

5 A Yes.

6 Q Based on your review of documents from Ethicon  
7 and the deposition testimony you reviewed and all the  
8 various things you reviewed in preparing for your  
9 deposition today, do physicians who utilize the TVT  
10 Secur have adequate information to conduct a  
11 risk/benefit analysis?

12 MR. HUTCHINSON: Object to form.

13 THE WITNESS: Based on the information I've  
14 reviewed? No.

15 BY MR. LUNDQUIST:

16 Q And you actually went through today and  
17 discussed some of the data that you have access to that  
18 the average urogynecologist or OB-GYN would not have,  
19 fair?

20 A That's correct.

21 Q And certainly based on your review of  
22 Dr. Walss' deposition, you can appreciate that there was  
23 a lot of information that we've discussed today that he  
24 did not have access to.

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1 performs as intended, in terms of the risk versus  
2 benefit. So clinical trials are required for certain  
3 devices before they get cleared.

4 Q Part of that would be to establish a -- would  
5 you agree that part of that would be to establish a  
6 favorable risk/benefit ratio?

7 A To help develop the IFU, yes, and to also give  
8 the label information. Some manufacturers do clinical  
9 trials beforehand to get -- so they have it for  
10 marketing; they can make claims in terms of benefits.

11 Q And in terms of your methodology in that  
12 opinion, do industry guidelines and standards inform  
13 your methodology with respect to that opinion?

14 A Yes.

15 Q And that would include the GHFTF standards that  
16 you cited in your reliance list?

17 A Yes, as well other -- other industry  
18 standards, such as biocompatibility standards, testing  
19 standards. There's all kinds of ISO standards, and AAMI  
20 standards. So international, United States, industry  
21 standards.

22 Q That would include your work consulting with  
23 industry?

24 A Yes, and it began in my work with the FDA,

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1 MR. HUTCHINSON: Leading.

2 BY MR. LUNDQUIST:

3 Q Correct?

4 A Yes.

5 Q And you had to sign a confidentiality order to  
6 be able to review these documents?

7 A Yes, sir.

8 Q You also reviewed deposition testimony from  
9 Ethicon employees, correct?

10 A Yes, sir.

11 Q And is that deposition testimony something  
12 that the average urogynecologist or OB-GYN who implants  
13 Ethicon products is going to have at hand?

14 A No.

15 Q Is your opinion that a manufacturer could be  
16 obligated to do pre-market clinical trials under  
17 industry guidelines even if the FDA doesn't require a  
18 510(k) process?

19 A Yes, as part of design development under 21  
20 C.F.R. 20.

21 Q What is the basis for that opinion besides a  
22 requirement under 21 C.F.R. Part 20?

23 A Well, and also to ensure that they sell a safe  
24 and effective product and make sure that it actually

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1 I got involved in standards organizations, looking at  
2 standards for the FDA, and then after I left FDA, I was  
3 a reviewer of voluntary standards for various industry  
4 groups.

5 Q Can clinical trials of similar products be  
6 instructive in evaluating the safety and efficacy  
7 profile of a device?

8 A Yes.

9 Q And so would it be fair to say that while it  
10 may be instructive, it would not be appropriate to  
11 solely rely on that?

12 MR. HUTCHINSON: Objection, leading.

13 THE WITNESS: Yeah, if there's significant  
14 differences, you have to take into consideration what  
15 are the differences and how will they potentially change  
16 the safety and effectiveness.

17 BY MR. LUNDQUIST:

18 Q And what types of differences are you talking  
19 about, particularly in the context of the TVT Secur?

20 A Well, in terms of the change in the mesh that  
21 we went through at 8 centimeter; that you're using  
22 Ethisorb as a fixation component, or the Christmas tree  
23 formation, which is new -- we haven't talked about  
24 that -- to stabilize the mesh; that you're using a new

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1 inserter that is sharp as opposed to the other inserter;  
 2 that you're saying that this device can be used for  
 3 either a retropubic or a hammock configuration, which  
 4 was new, that one mesh would be sold for both. I went  
 5 into some of that.

6 Q Okay. So in other words, when you are talking  
 7 in your designation -- you testified somewhat today, but  
 8 when you're trying to determine whether a product is  
 9 safe and effective, separate and apart from looking at  
 10 clinical data from similar products, you would also look  
 11 at, if they were done, pre-market clinical studies on a  
 12 particular product.

13 A Right, right. You could also begin looking at  
 14 the literature, the medical literature, for other  
 15 products that are similar to what you're considering.  
 16 So it's not just your own products. You can look at  
 17 what other -- the history of other products.

18 Q And this is the methodology that you employed  
 19 as a medical officer within the FDA as well, fair?

20 MR. HUTCHINSON: Objection, leading.

21 THE WITNESS: Well, yes, and this is the  
 22 methodology that manufacturers employ and the FDA  
 23 anticipates they will employ when you have them come  
 24 for -- industry come in for meetings. You ask them,

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1 A Yes, it continued on.

2 Q So we talked about the various industry  
 3 standards separate and apart from the FDA regulations  
 4 and guidance documents that you've utilized, right?

5 A Yes.

6 Q Okay. Can clinical -- strike that. Can  
 7 industry standards and guidelines require pre-market  
 8 clinical trials, even though they don't specifically  
 9 call out polypropylene transvaginal mesh?

10 A Yes, and also the medical literature, the  
 11 history of the product, devices, all of these things  
 12 have to be taken into consideration, particularly if  
 13 you're changing the device.

14 Q Why?

15 A Because you have to ensure that it's going to  
 16 work in terms of the patient, it's going to do what it's  
 17 supposed to do, and there are many new features with  
 18 this product that needed to be addressed.

19 Q So in addition to the testimony you've given  
 20 as to why you believe Ethicon should have conducted  
 21 pre-market clinical trials, do you have.... Well,  
 22 strike that. What is HAS?

23 A HAS is a French organization that did a review  
 24 of the types of studies that needed -- information that

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1 "What did you look at?" if they have a meeting, and  
 2 they'll usually talk about animal data, studies that  
 3 they've done, other similar studies, industry standards.  
 4 FDA allows companies to cite certain industry standards.  
 5 So yeah, that's the typical process around designing a  
 6 medical device.

7 BY MR. LUNDQUIST:

8 Q Okay, you told me just a minute ago that  
 9 industry standards and guidelines informed your  
 10 methodology and your opinion on whether or not  
 11 pre-market clinical trials are necessary for the TVT  
 12 Secur.

13 A Well, it's not just that. That would  
 14 contribute, but also my experience as a physician, and  
 15 my knowledge and training as to what the potential risks  
 16 are to human beings. So those would also feed into it.

17 Q After leaving the FDA -- well, let me ask you  
 18 this: While you were at the FDA, were you on these  
 19 types of industry standards committees?

20 A Yes, I was assigned, particularly in the  
 21 Office of Health Affairs, to be involved in standards  
 22 committees.

23 Q And then after leaving the FDA, were you ever  
 24 on an industry standards committee?

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1 needed to be for pelvic procedures, and I think the name  
 2 is the French National Authority for Health, HAS.

3 Q And that was listed in your reliance list, was  
 4 it not?

5 A Yes.

6 Q That's something you relied on in rendering  
 7 your opinions in this matter?

8 A Yes. And you asked about standards also  
 9 supporting pre-clinical. It was also the company's  
 10 documents and their own internal discussion that they  
 11 needed clinical data before they had it launched.

12 MR. HUTCHINSON: Move to strike as  
 13 nonresponsive.

14 BY MR. LUNDQUIST:

15 Q So we're clear, the HAS is not the FDA  
 16 equivalent in France; is that fair?

17 MR. HUTCHINSON: Objection, leading.

18 THE WITNESS: I don't believe it is. Now, let  
 19 me look. I'm not sure. It could be. I don't want to  
 20 say it isn't. I'm not sure what their FDA is called.  
 21 This is their national authority for health. So it may  
 22 be their FDA equivalent. I know they have a different  
 23 name, but that may somehow be connected to them.

24 // //

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1 BY MR. LUNDQUIST:

2 Q Just so we're clear -- I think you have  
3 testified to this -- when you were formulating your  
4 opinions on whether or not pre-market clinical trials  
5 were necessary for the TVT-S, you relied on this HAS  
6 study, did you not?

7 MR. HUTCHINSON: Objection, leading.

8 THE WITNESS: Yes. There's a HAS study that  
9 is similar to the NICE study, in that they're talking  
10 about funding. Their focus is on funding of effective  
11 procedures. So I believe that's where HAS comes in.

12 BY MR. LUNDQUIST:

13 Q Okay, well, back up. What is NICE?

14 A NICE is a group in the United Kingdom that  
15 looks at the efficacy of products that are offered for  
16 treatment, and they get into whether they're going to  
17 fund it in terms of socialized medicine. So they're  
18 actually technology-assessment types of organizations.

19 Q Oh, there it is, and that's also listed on  
20 your reliance list as having reviewed this document to  
21 substantiate these opinions you've given today?

22 A Right.

23 Q The National -- the National Institute for  
24 Health Care Excellence?

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1 THE WITNESS: Not unless FDA adopts them  
2 specifically, and then they often oftentimes will issue  
3 something that they have adopted.

4 BY MR. LUNDQUIST:

5 Q And the same would be true for the ISO  
6 standards that you talked about earlier; those are not  
7 federal regulations?

8 A Those are not federal regulations. FDA will  
9 allow certain ones to be used by manufacturers. FDA  
10 kind of picks and chooses which consensus documents  
11 they're going to accept in the standards.

12 Q You were asked some questions by counsel about  
13 your opinions on the types of pre-market trials and  
14 pre-market data that needed to be done by Ethicon prior  
15 to marketing its products. Do you recall that?

16 A Yes.

17 Q Your opinions on the types of trials and the  
18 types of testing and the types of data that Ethicon  
19 should have done prior to commercialization are not  
20 based solely on what you want; is that fair?

21 A Well, they're not subjective opinions.  
22 They're based on the company's documents and also some  
23 of the issues of safety and effectiveness. The HAS  
24 document actually talks about the type of information

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1 A Yes. It's a technology assessment.

2 Q The GHTF guidelines that you reviewed, are  
3 those guidelines still utilized in industry today?

4 A Yes, because products are now becoming more  
5 global, and so the FDA and different regulatory agencies  
6 are trying to harmonize requirements and the procedures  
7 and processes that manufacturers do, to try to have some  
8 overlap, so that there's a consistency with the types of  
9 requirements for marketing product.

10 Q Do you have personal knowledge as to whether  
11 the industry -- strike that. Do you have personal  
12 knowledge as to whether industry had any input into the  
13 formulation of those guidelines?

14 A Industry typically does, but it's also through  
15 the regulatory bodies that are on those different  
16 panels. So industry does, because they also sit on  
17 those panels, but the regulatory bodies do, too.

18 Q In your consulting work with industry, do you  
19 utilize the GHTF -- did you utilize the GHTF guidelines?

20 A Yes, yes, especially for post-market  
21 surveillance for devices.

22 Q And so we're clear, the GHTF guidelines are  
23 not federal regulations, are they?

24 MR. HUTCHINSON: Objection, leading.

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1 that should be obtained. So they're from various  
2 sources.

3 Q So did you -- so essentially, did you rely on  
4 industry guidelines to inform you what would be an  
5 appropriate pre-market clinical trial?

6 A That would be that, and also company documents  
7 in terms of what they've done, and also my own training  
8 and experience looking at similar types of issues for  
9 the FDA, for clinical trials.

10 Q Now, in order to -- in terms of the labeling  
11 of the IFU in regard to the TVT Secur, in order to use  
12 the device safely, do you need to know about the  
13 severity of the complications?

14 A The labeling -- yes, the labeling is supposed  
15 to indicate the severity and the frequency, and it's not  
16 just the IFU, it's also the marketing. The marketing has  
17 to be consistent with the potential risks and benefits.  
18 You can't overstate benefits and not give the risk  
19 information.

20 Q And so we're clear, nowhere in the IFU that  
21 you looked at today does it talk about severity,  
22 permanence or frequency of the adverse events, does it?

23 A Right, and that's the information you  
24 originally get cleared, but you get that information as

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1 the product is being used, and the label is a living  
 2 thing. It's supposed to be updated with your  
 3 post-market information for physicians. They call it  
 4 the Total Product Life Cycle, TPLC, that the  
 5 manufacturer updates their labels.  
 6 Q And that type of information is information  
 7 the investigator would need to know to be able to  
 8 appropriately -- strike that.  
 9 Whose responsibility is it to ensure that the  
 10 information is -- adequate information is contained in  
 11 the instructions for use?  
 12 MR. HUTCHINSON: Objection, form.  
 13 THE WITNESS: The manufacturer.  
 14 BY MR. LUNDQUIST:  
 15 Q You can answer.  
 16 A The manufacturer, according to the Act and  
 17 implementing regulations.  
 18 Q And who writes the IFU?  
 19 A The manufacturer, and they could update it at  
 20 any time.  
 21 Q And separate and apart from FDA regulations  
 22 that you talked about, if a complication is potentially  
 23 going to be permanent, and that is a foreseeable risk by  
 24 the manufacturer, should it be included, based on

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1 BY MR. LUNDQUIST:  
 2 Q What is the basis of your opinions on  
 3 post-market surveillance that you've given today?  
 4 A It's particularly having worked in OHA in the  
 5 post-market surveillance group -- I mean, the  
 6 post-marketing issues, and having dealt with MDRs and  
 7 follow-up and looking at adequacy of warnings and  
 8 labeling. So that was what I was involved in in the  
 9 first couple years, and then I continued on, since I was  
 10 first trained in it.  
 11 Q Does the length of.... One of the categories  
 12 you were designated on is the literature reflecting the  
 13 problems that surgeons were experiencing with the TVT  
 14 Secur.  
 15 A That should be added to the list.  
 16 MR. HUTCHINSON: Objection, form.  
 17 BY MR. LUNDQUIST:  
 18 Q And -- well, let's just ask. What is the  
 19 basis for your opinion that the literature reflected  
 20 that surgeons were experiencing problems with the TVT  
 21 Secur?  
 22 A Well, the published literature was, and then  
 23 the KOLs, people discussing it with the -- it's based on  
 24 the company documents and information -- where are you?

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1 industry guidelines, in the instructions for use?  
 2 A Yes. In terms of adequate warnings, yes.  
 3 Q And the same would be true with respect to  
 4 severity?  
 5 MR. HUTCHINSON: Objection, leading.  
 6 THE WITNESS: Yes.  
 7 BY MR. LUNDQUIST:  
 8 Q Frequency?  
 9 MR. HUTCHINSON: Leading.  
 10 THE WITNESS: Right. Well, an adequate label  
 11 is supposed to have that information.  
 12 MR. HUTCHINSON: Move to strike as  
 13 nonresponsive.  
 14 BY MR. LUNDQUIST:  
 15 Q And with respect to your opinions on labeling,  
 16 have you ever referred to and used and relied on  
 17 industry guidelines, separate and apart from the FDA  
 18 regulations?  
 19 A Yes. That's part of my training. I'm trained  
 20 in those.  
 21 Q The same would be true for your opinions on  
 22 post-market surveillance?  
 23 MR. HUTCHINSON: Leading.  
 24 THE WITNESS: Yes.

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1 Q It's on page 13, middle of 13.  
 2 A Yes, it would be based on the company  
 3 documents and also the -- from the physicians, and then  
 4 you look at the Cochran report. The Cochran report  
 5 actually did a randomized controlled study and review  
 6 and set out the potential risks, and that wasn't in the  
 7 labels. So they actually looked at all the literature  
 8 for us and said that there were -- needed to be  
 9 warnings.  
 10 Q Okay, and we're talking about the warnings,  
 11 the -- obviously, you believe the Instructions for Use  
 12 was inadequate related to the TVT Secur.  
 13 MR. HUTCHINSON: Objection, leading.  
 14 THE WITNESS: It was inadequate because it  
 15 wasn't being updated. It first got cleared, and then as  
 16 more information was coming, particularly in 2007, 2008,  
 17 that information wasn't being added. Even before it was  
 18 launched, it wasn't updated, in terms of the first  
 19 amendment for the design validation. The doctors said,  
 20 update the IFU. Internally, the company's doctors are  
 21 saying, update the IFU, the Instructions For Use, and  
 22 they weren't updating the information.  
 23 So internally, the company was saying it.  
 24 I think Dan Smith was the one primarily not wanting to

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1 update the information. There was discussion about  
2 needing a "cookbook" to teach the doctors how to put the  
3 devices in, and that wasn't being done in terms of the  
4 labels, and it was never updated.

5 MR. HUTCHINSON: Move to strike as  
6 nonresponsive.

7 BY MR. LUNDQUIST:

8 Q And so the inadequacy of the warning --

9 MR. HUTCHINSON: I'm sorry, did you get my  
10 objection?

11 THE REPORTER: Yes, I did.

12 BY MR. LUNDQUIST:

13 Q The inadequacy of the warnings that you've  
14 talked about today, that's not just based on the FDCA;  
15 that's based on these other guidelines and standards  
16 that we've talked about. Is that fair?

17 MR. HUTCHINSON: Object to form.

18 THE WITNESS: Well, it's based on other  
19 guidelines and standards. It's also based on my  
20 experience as a physician and training as a physician  
21 being able to understand what's being reported, in that  
22 a physician needs to know that information. And it's  
23 further supported by Dr. Miklos.

24 // //

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1 the medical literature. That's where my training and  
2 experience in looking at literature comes from.

3 Q Would pre-market clinical trials, if designed  
4 appropriately, give us information on frequency of  
5 complications?

6 A Yes.

7 Q How do you know that?

8 A Well, especially because the reports were  
9 actually coming at 12 weeks in terms of failures. So  
10 even a short-term trial, less than a year, would come up  
11 with this information.

12 Q And would a pre-market clinical trial, if  
13 designed appropriately, also give you information on --  
14 strike that.

15 But would a pre-market clinical trial, if  
16 designed appropriately, give us information on the  
17 severity of complications?

18 A Yes.

19 Q Obviously, that would be before the product  
20 was placed on the market.

21 A Correct.

22 MR. HUTCHINSON: Objection, form.

23 THE WITNESS: And then the company proposed to  
24 have a registry to give that information, which they

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1 BY MR. LUNDQUIST:

2 Q So with respect to your opinions on labeling,  
3 have you referred to and used and relied on industry  
4 guidelines, separate and apart from FDA regulations?

5 A Yes.

6 Q Okay, and the same --

7 A And adequate labels and discussion of adequate  
8 labels, yes.

9 Q Sure. Same would be true for your opinions on  
10 post-market surveillance?

11 MR. HUTCHINSON: Objection to form.

12 THE WITNESS: Correct, and that would also  
13 come under corrective and preventive action, when you're  
14 having issues, but that's FDA, again.

15 MR. HUTCHINSON: Move to strike as  
16 nonresponsive.

17 BY MR. LUNDQUIST:

18 Q Talking about the literature, would the length  
19 of a study play a role in whether or not you can  
20 determine if a particular patient might have future  
21 complications?

22 A Yes, totally, and you have to take that into  
23 consideration, is it six weeks versus twelve weeks, or  
24 if it's a follow-up. So you have to be able to review

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1 didn't follow through. That was -- the TVT world was  
2 listening, but they didn't follow up with it.

3 MR. HUTCHINSON: Objection, nonresponsive.

4 BY MR. LUNDQUIST:

5 Q Is it possible for an industry guideline to  
6 take into account every single medical device and then  
7 give you a list of exactly what type of -- or kind of  
8 trial needs to be done?

9 MR. HUTCHINSON: Form.

10 THE WITNESS: No, no. The company is  
11 responsible for their own design. Because there's so  
12 many types of devices, so many types of issues, the  
13 manufacturer is the expert. The manufacturer has to  
14 take into consideration the potential risks. They look  
15 at the literature, other similar trials, and they design  
16 what they need to look at in terms of their product.

17 But no, I don't know of any government agency  
18 or industry standard that is specific for all medical  
19 device manufacturers, because of the variety of devices.

20 MR. LUNDQUIST: Doctor, I think that's all the  
21 questions I have. I'll pass the witness.

22 MR. HUTCHINSON: Assuming, Cynthia, you don't  
23 have any follow-up questions, is that correct? Cynthia  
24 Freeman?



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1 MS. FREEMAN: Yeah, that's right, I don't have  
 2 any.  
 3 MR. HUTCHINSON: Okay, I've got just a couple.  
 4 FURTHER EXAMINATION BY MR. HUTCHINSON  
 5 BY MR. HUTCHINSON:  
 6 Q Dr. Parisian, according to your reliance list,  
 7 you relied on the GHTF guidelines, correct?  
 8 A Yes, sir.  
 9 Q And these are standards that relate to safety?  
 10 A Yes, sir.  
 11 Q These are standards that apply to Ethicon's  
 12 products?  
 13 A Worldwide products, yes, sir.  
 14 Q Including TVT Secur?  
 15 A All of them.  
 16 Q And these standards are mandatory for Ethicon  
 17 to follow, correct?  
 18 A No. They're mandatory for them to consider  
 19 and then create their own procedures that would be  
 20 adherent to them wherever they want to market their  
 21 product.  
 22 Q I asked you earlier about your participation  
 23 as a subject in a clinical trial. Have you ever  
 24 designed a clinical trial for any type of gynecological

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1 product?  
 2 A Not for a gynecological product. I was  
 3 required at FDA to design -- oh, wait a second. That's  
 4 basically right, in terms of that, because breast cancer  
 5 is not really gynecological. You were talking about  
 6 pelvis.  
 7 Q And you have never helped with a clinical  
 8 trial in any type of urology, correct?  
 9 A That's correct, yes.  
 10 MR. HUTCHINSON: I don't have any further  
 11 questions. Thank you for your time.  
 12 THE WITNESS: Can I clarify one other thing?  
 13 You asked me about bankruptcy and suits. My husband has  
 14 filed bankruptcy, and there's been some suits against  
 15 him, lawsuits against him.  
 16 MR. LUNDQUIST: I don't think he asked you  
 17 that.  
 18 THE WITNESS: No, but I wanted to clarify for  
 19 him that I wasn't saying no, but they were my husband's,  
 20 so I don't know anything about those.  
 21 BY MR. HUTCHINSON:  
 22 Q Well, when did your husband file bankruptcy?  
 23 MR. LUNDQUIST: Form.  
 24 MR. HUTCHINSON: What's the matter with the

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1 form, counsel?  
 2 MR. LUNDQUIST: It's completely irrelevant.  
 3 THE WITNESS: Well, no, he filed bankruptcy  
 4 years ago. I don't know, I think like 10 -- 10, 11  
 5 years ago. I didn't. I don't know anything about it,  
 6 but I don't know -- I'm not -- the specifics of it.  
 7 BY MR. HUTCHINSON:  
 8 Q How much money -- were you and your husband  
 9 married back in 2000?  
 10 A Yes, sir.  
 11 Q How much, back in 2000, how much money were  
 12 you making then, doing litigation services?  
 13 A About -- I don't know, 400,000, 500,000.  
 14 MR. HUTCHINSON: All right, no further  
 15 questions. Thanks.  
 16 Before everybody goes -- and why don't we stay  
 17 on the record -- let the record reflect that we have 16  
 18 exhibits, and what we'll do is, plaintiff's counsel and  
 19 I will try to make sure we have all of them together,  
 20 and then we'll get back the record.  
 21 (Discussion off the record.)  
 22 MR. HUTCHINSON: All right, so we're back on  
 23 the record. Let the record reflect that we have 16  
 24 exhibits attached to this deposition, and that

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1 plaintiff's counsel, and I as counsel for Ethicon, have  
 2 both looked at the exhibits and believe that they are  
 3 complete. Is that right?  
 4 MR. LUNDQUIST: That's fair.  
 5 MR. HUTCHINSON: All right, thanks. That's  
 6 all we have.  
 7 THE REPORTER: Okay.  
 8 MR. HUTCHINSON: Wait, back on the record.  
 9 And let's also make a record that the two big  
 10 black binders that have tabs in one of them, 1 through  
 11 69, and 1 through 23 in another one, are going to be  
 12 given to the court reporter, let him have possession of  
 13 these for him to make sure that complete and color  
 14 copies are made, and that he will be responsible for  
 15 submitting them directly to the witness. Okay? Thank  
 16 you.  
 17 (Deposition concluded at 4:20 p.m.)  
 18 ---o0o---  
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## 1 CERTIFICATE

2  
3 I, LEO T. MANKIEWICZ, CR, a Certified  
4 Reporter in the State of Arizona, do hereby certify that  
5 an oath was duly administered to the witness Suzanne  
6 Parisian, M.D., pursuant to A.R.S. §41-324(B) and that  
7 the foregoing pages constitute a full, true, and  
8 accurate transcript of the proceedings had in the  
9 foregoing matter, all done to the best of my skill and  
10 ability.

11 The witness herein, Suzanne Parisian,  
12 M.D., has requested signature.

13 SIGNED and dated this 20th day of  
14 February, 2015.

15  
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17  
18 LEO T. MANKIEWICZ, CR, RMR, CRR  
19 Certified Reporter  
Certificate No. 50778  
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## 4 PAGE LINE CHANGE

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## 1 INSTRUCTIONS TO WITNESS

2  
3 Please read your deposition  
4 over carefully and make any necessary  
5 corrections. You should state the reason  
6 in the appropriate space on the errata  
7 sheet for any corrections that are made.

8 After doing so, please sign  
9 the errata sheet and date it. It will be  
10 attached to your deposition.

11 It is imperative that you  
12 return the original errata sheet to the  
13 deposing attorney within thirty (30) days  
14 of receipt of the deposition transcript  
15 by you. If you fail to do so, the  
16 deposition transcript may be deemed to be  
17 accurate and may be used in court.  
18  
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## 1 ACKNOWLEDGMENT OF DEPONENT

2 I, \_\_\_\_\_, do  
3 hereby certify that I have read the  
4 foregoing pages, and that the same  
5 is a correct transcription of the answers  
6 given by me to the questions therein  
7 propounded, except for the corrections or  
changes in form or substance, if any,  
noted in the attached Errata Sheet.

8 SUZANNE PARISIAN, M.D. DATE

9  
10  
11  
12  
13  
14  
15 Subscribed and sworn  
to before me this  
\_\_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_.

16 My commission expires: \_\_\_\_\_

17 Notary Public

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